

“ENHANCING DIABETES SELF-MANAGEMENT:
MOTIVATIONAL ENHANCEMENT THERAPY”

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Abstract

The effectiveness of Motivational Enhancement Therapy (MET), a brief four session form of Motivational Interviewing (MI), provided by diabetes health practitioners at a hospital-based clinic, in improving diabetes outcome and self-management of Type 1 and Type 2 diabetes was evaluated using quasi-experimental designs (i.e., non-random control group and multiple baseline designs). Study 1 evaluated if MET provided by Diabetes Nurse Educators (DNEs) was effective in improving diabetes outcome (i.e., blood glucose and lipids) and diabetes self-management, and compared its effectiveness to the current standard treatment which comprised Patient Education (PE). Study 2 evaluated if the results of Study 1 could be generalised to Dietitians providing the intervention. Study 3 evaluated the effects of MI training and post-training supervised practice on practitioner and patient behaviour. Specific hypotheses (Studies 1-2) were that MI would lead to improved diabetes outcome through improved diabetes self-management, and would be more effective than PE. Further, training in MI plus supervised practice was predicted to lead to Nurse Educators behaving in ways consistent with MI and as a result the participants would exhibit less resistance and increased change talk than participants receiving PE (Study 3).

The results suggest that MET was well received by the participants, and contributed to improved diabetes outcome (e.g., lowered blood glucose) and diabetes self-management (e.g., self-monitoring of blood glucose and dietary compliance), and may have been more effective than PE, although high variability made conclusions uncertain. Evidence of generalisation across participants, intervention staff, and

outcomes is provided. Additionally, evidence is provided that with two days training plus supervised practice the DNE were able to practice MET to at least a beginning level of competency in MI and that as a result the participants behaved in ways consistent with MI theory (i.e., showed less resistance and increased change talk).

Executive Summary

Diabetes is a major risk factor for nerve damage (leading to impotence and foot problems), stroke, heart attack, heart failure and early death. In New Zealand diabetes is the leading cause of blindness, kidney failure and lower extremity amputation. Currently diabetes affects approximately 200,000 (i.e., 4%) New Zealanders (Ministry of Health, 2006), but it is predicted that there will be a 40% increase in the incidence diabetes by the year 2020 (Diabetes New Zealand, 2006).

Treatment of diabetes focuses on establishing and maintaining blood glucose levels within the normal range, thereby reducing the risk of complications. This requires the person with diabetes to engage in a wide range of self-care behaviours, some of which are new behaviours (monitoring blood glucose, injecting insulin) and others which involve lifestyle change (dietary modification, physical activity). PE has been the main way in which these changes have been promoted, but education alone appears insufficient for some people, and the best method for encouraging adherence is unclear.

There is evidence that more patient-centred approaches to health care consultations may have better outcomes than traditional advice-giving, particularly when lifestyle change is involved. MI is a directive, patient-centred approach that was developed initially as a brief intervention in the addictions field, but is gathering increased interest in health settings. It aims to motivate patients to make changes rather than provide detailed, step-by-step advice about behaviour change, and

provides a way of working with patients who may not seem ready to make the behaviour changes that are considered necessary by the health practitioner.

The aim of the present research was to evaluate the effectiveness of MET, a brief four session form of MI, in improving diabetes self-management, and to compare MET with PE. The research comprised three interrelated studies. Study 1 was an initial treatment evaluation. Study 2 aimed to test the generalisability of the results from Study 1, and Study 3 was an evaluation of the training and therapy process.

The research was conducted in a naturalistic setting, with diabetes health practitioners providing the intervention to participants with diabetes who had been referred for assistance because they had been experiencing difficulties with diabetes self-management. A variety of measures were used. These included primary outcome measures of metabolic control (blood glucose and lipids), and intermediate process variables, which comprised diabetes self-management behaviour, psychosocial measures (i.e., diabetes knowledge, emotional adjustment, personal models of diabetes, motivation to change, and treatment satisfaction), and measures of therapy process and treatment integrity.

The research is an example of both practice-based research (Glasgow et al., 2006) and the scientist-practitioner model of clinical psychology (Raimy, 1950) in practice. Action research methods (Boog, Keune & Tromp, 2003) were used in the development of the research, and quasi-experimental designs (non-random control group comparison and single-case research design) were used.

The results tentatively suggest that MET, conducted by nurse educators and dietitians in a hospital-based clinic, has promise as an effective intervention to enhance diabetes self-management, which contributes to improved diabetes outcome. Evidence is also provided that MET was well-received by the participants, and contributed to increased motivation, and a decrease in concern about the current seriousness of diabetes, concern about future complications and the effect on their lives. Additionally, process measures suggest that during MET the diabetes health practitioners behaved in ways consistent with MI, and this in turn appears to have elicited behaviour (i.e. fewer types of resistance behaviour, more signs of readiness to change, and increased change talk) consistent with predictions from previous MI research. The strengths and limitations of the present research are discussed, and recommendations are made for future research.

List of Abbreviations

ADA	American Diabetes Association
BMI	Body Mass Index
BT	Behaviour therapy
CBT	Cognitive-behavioural therapy
CI	Confidence interval
CV	Coefficient of variation
DCU	Drinker's check-up
DKT	Diabetes knowledge test
DNE	Diabetes nurse educator
ES	Effect size
GCC	Goals for change checklist
GP	General practitioner
HbA1c	Glycated haemoglobin
HBM	Health belief model
IDDM	Insulin dependent diabetes mellitus
MET	Motivational enhancement therapy
MI	Motivational interviewing
MICO	Motivational interviewing consistent response
MIKT	Motivational interviewing knowledge test
MIN	Motivational interviewing inconsistent response
MISC	Motivational interviewing skill code
NHST	Null hypothesis statistical testing
NDDM	Non-insulin dependent diabetes mellitus

PAID.....	Problem areas in diabetes
PAR	Participatory action research
PBT.....	Practice-based behavioural trial
PCT.....	Practice-based clinical trial
PE	Patient education
PMDI.....	Personal models of diabetes interview
PMDQ	Personal models of diabetes questionnaire
RC.....	Reliable change index
RCT	Randomised controlled trial
RFIC	Risk factor identification checklist
SDSCAQ.....	Summary of Diabetes Self-Care Activities Questionnaire
SMOBG.....	Self-monitoring of blood glucose
SOCRATES	Stages of change readiness and treatment eagerness scale
TAU	Treatment as usual
TEI.....	Treatment evaluation inventory
%CCT.....	Percent client change talk

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Diabetes: Disease and Psychosocial Treatment

As noted above, this thesis is about a novel intervention (MI) applied to a specific chronic health condition, diabetes. This chapter provides an overview of diabetes and its treatment, including diabetes self-management, PE, and psychological interventions, as well as an overview of MI, including research on its application to health behaviour change and diabetes in particular.

Diabetes

Diabetes is a group of disorders which comprise hyperglycaemia and glucose intolerance, due to insulin deficiency, impaired effectiveness of insulin action, or both (Harris & Zimmet, 1997). There are two major categories of diabetes (Amos, McCarty & Zimmet, 1997), Type 1 (or insulin dependent diabetes mellitus – IDDM) and Type 2 (or non-insulin-dependent diabetes mellitus – NIDDM).

Type 1 diabetes results from a loss of insulin production due to cellular-mediated autoimmune destruction of pancreatic islet beta-cells (Atkinson & MacLaren, 1994). While Type 1 diabetes can occur at all ages (Molbak, Christau, Marner, Borch-Johnsen & Nerup, 1994), it is one of the most common childhood diseases in developed countries (LaPorte, Matsushima & Chang, 1995).

Type 2 diabetes involves insulin resistance and insulin deficiency (Reaven, Bernstein, Davis & Olefsky, 1976; Turner, Holman, Matthews, Hockaday & Peto, 1979), although the specific reasons for the development of these are not yet known

(Amos et al., 1997). The diagnosis of Type 2 diabetes usually occurs after 40 years of age, although the age of onset is often 10 years earlier (Zimmet, Dowse, Finch, Serjeantson & King, 1990). Type 2 diabetes accounts for 50-85% of diabetes in developed countries (World Health Organisation, 1994) and for nearly all diabetes in developing countries (Amos et al., 1997), with higher rates of Type 2 diabetes within ethnic groups who have experienced a greater degree of westernisation (Amos et al., 1997)

Diabetes is one of the most common non-communicable diseases globally, and is the fourth or fifth leading cause of death in most developed countries, with evidence that it is epidemic in many industrialised and developing countries (Amos et al., 1997). The prevalence rate of diagnosed diabetes is estimated at 4% of New Zealanders 15 years and over, but with Maori and Pacific Island prevalence rates about three times higher than for other New Zealanders (Ministry of Health, 2006). Maori and Pacific Island people also have a low mean age at diagnosis of diabetes compared to Caucasians (McGrath, Parker & Dawson, 1999; Lunt, Lim, Crooke & Smith, 1990; Simmons, Gatland, Leakehe & Fleming, 1996). This means that they have a longer lifetime exposure to hyperglycaemia and therefore are at greater risk of developing complications related to hyperglycaemia (Moore & Lunt, 2000).

The clinical course and prognosis of diabetes is mainly influenced by the duration of diabetes and degree of metabolic control achieved (World Health Organisation, 1994). People with diabetes have reduced life expectancy (Finch & Zimmet, 1988; Panzram, 1987), and are at risk of microvascular (retinopathy, nephropathy and neuropathy), and macro-vascular (coronary heart disease or stroke)

complications, and peripheral vascular disease, such as infection or ulceration (Tuomilehto & Rastenyte, 1997). Diabetes is the leading cause of blindness in developed countries (Klein & Moss, 1992), and is the leading known cause of end-stage renal disease in New Zealand (Excell & McDonald, 2004), although diabetic neuropathy is probably the most common complication, occurring in 30-40% of people with Type 1 and Type 2 diabetes (World Health Organisation, 1994). In the United States diabetes contributes to a 15-fold increase in the risk of lower limb amputation. Recent studies (i.e., the Diabetes Control and Complications Trial, DCCT, Research Group, 1993; and United Kingdom Prospective Diabetes Study, UKPDS, Group, 1998), however, have demonstrated that strict control of blood glucose levels improves prognosis by reducing the severity and occurrence of complications of diabetes, including retinopathy and nephropathy.

Given that the prognosis is improved by strict control of blood glucose, the goal of diabetes (Type 1 and Type 2) treatment is to keep blood glucose levels as close to the normal range as possible (Drury, 1979) through the use of medication, which may involve oral hypoglycaemics or intensive insulin treatment requiring up to four or more injections per day, and a complex self-management regimen, including self-monitoring of blood glucose (up to four or more times a day), diet (low in fat and sugar, high in fibre) and regular exercise. People with diabetes are also encouraged to be vigilant for symptoms of hypo- or hyperglycaemia, engage in foot care, and attend frequent medical appointments. In addition, because of the relationship between diabetes and cardiovascular complications (UKPDS Group, 1998), diabetes management also includes an emphasis on reducing cardiovascular risk factors, such as hypertension and dyslipidaemia (i.e., a disturbance in lipids).

Diabetes Self-Management

Self-management within the health behaviour change literature refers to ‘self-regulation or self-monitoring behaviours’ (Nieuwenhuijsen, Zemper, Miner & Epstein, 2006, p.247), aimed at ‘softening the impact of long-term disease and disability by eliminating or reducing impairments, disability, and handicap, minimising suffering and maximizing potential years of useful life (Last, Spasoff, Harris & Thuriaux, 2001, p.142). Being self-regulating means being observant and making judgements based on observation, and then attempting to change one’s own behaviour in order to achieve a desired goal or end point (Clark, Gong & Kaciroti, 2001). Self-management behaviour comprises the individual’s efforts to keep the disease and its effects under control, which may or may not be consistent with health practitioners’ recommendations (Karoely & Kanfer, 1982; Clark et al, 2001).

Diabetes self-management is a complex process in which the individual with diabetes engages in a set of skilled behaviours in order to manage their diabetes (Gonder-Frederick, Cox & Ritterband, 2002; Goodall & Halford, 1991). ‘Active ongoing decision making’ (Gonder-Frederick et al., 2002, p.613) is an integral part of diabetes self-management as individuals with diabetes ‘frequently confront situations with multiple response options and no single right solution (Gonder-Frederick et al., 2002, p.613), as well as there being considerable variability in the individual level of self-care required across different aspects of diabetes treatment and over time (Gonder-Frederick et al., 2002).

The finding from the DCCT (DCCT, 1993) and UKPDS (Turner, Cull & Holman, 1996; UKPDS Group, 1998) that strict control of blood glucose levels improves prognosis has led to most people with diabetes being expected to follow long term, demanding, and intensive treatment regimens that previously were only recommended for those who were considered highly motivated and diligent in their self-management of their diabetes (Gonder-Frederick et al., 2002). Perhaps not surprisingly, levels of adherence to diabetic regimens is typically low (Ary, Toobert, Wilson, & Glasgow, 1986; Grossman, Brink & Hauser, 1987), with diet and exercise the most difficult to manage (Glasgow, McCaul & Schafer, 1987).

Since the complications of diabetes result from inadequate glycemic control and 99% of diabetes treatment comprises self-management of varying levels (Coles, 1996), the potential benefits from assisting those with poor self-management are considerable (Gage, et al., 2004). Yet, few predictors of effective diabetes self-management have been identified (Goodall & Halford, 1991), with demographic variables (e.g., gender, ethnicity, income and education), the number and length of appointments, treatment satisfaction and knowledge about diabetes self-management not usually predicting effective versus less effective self-management (Mazzuca, 1982; Watts, 1980). Complex psychological constructs, namely health beliefs (Brownlee-Duffleck, Peterson, Simonds, Goldstein, Kilo & Hoette, 1987) and self-efficacy (Glasgow, Toobert, Riddle, Donnelly, Mitchell & Calder, 1989; Grossman, Brink & Hauser, 1987) have, however, been found to predict diabetes self-management. Health beliefs, for example, have been found to account for 41-50% of the variance in reported self-management (Harris & Linn, 1985; Wilson, Ary, Biglan, Glasgow, Toobert & Campbell, 1986), and self-efficacy has been found to have

significant effect, even when controlling for the strong predictive effect of past levels of self-management (Kavanagh, Gooley & Wilson, 1993). Additionally, personal models of diabetes (Hampson, Glasgow & Toobert, 1990), specifically beliefs about the seriousness of diabetes and effectiveness of its treatment, have been found to be associated with improved self-management (Brown & Hedges, 1994; Hampson, Glasgow & Strycker, 2000).

Studies of diabetes self-management, however, are challenged with the issue of reliable measurement (Goodall & Halford, 1991), with diet and exercise the most difficult aspects of diabetes treatment to measure (Glasgow et al., 1987). For example, defining poor dietary management is difficult given the complex nature of diabetic dietary recommendations (Glasgow, Wilson & McCaul, 1985), and different aspects of diet may have different effects on blood glucose (Goodall & Halford, 1991). Additionally, self-report, which can be unreliable, has tended to be the main means of measuring diet and exercise (Glasgow et al., 1985). As a result, ‘most studies have operationalised self-management as a single global index of compliance to treatment’ (p.2), with all aspects of the diabetes treatment combined into this single measure of self-management (Goodall & Halford, 1991). Instead, Goodall and Halford (1991) suggest that there needs to be diabetes self-management studies that demonstrate measurable improvements in self-management behaviour that lead to improvement in blood glucose.

Fulfilling this recommendation has been assisted by technological advances that have provided alternative and better validated measures of diabetes self-management behaviour. For example, home blood glucose monitors which include

memories that record time, date and test results, provide a better validated means of measuring blood glucose and testing behaviour (Goodall & Halford, 1991).

Similarly, activity monitors have been used to measure exercise intensity and duration (Glasgow et al., 1987) and 'sophisticated ambulatory computers' (Goodall & Halford, 1991, p.2) have been used to measure both diet and exercise (Burnett, Taylor & Agras, 1987). While these technological advances are welcome, nevertheless they have not solved the challenges of self-management in diabetes.

Patient Education

The main widely adopted strategy for assisting with diabetes self-management has been through PE, which comprises the provision of knowledge and advice about diabetes and diabetes self-management, although PE interventions greatly vary in how many sessions are used and how much patient involvement there is. PE is accepted as an important component of chronic disease management (Rosenberg, 1976), and has been considered an important component of diabetes treatment (Brown, 1990), with the assumption that increased knowledge will lead to improved self-management. Research shows that PE does improve patients' knowledge about diabetes (Brown, 1988, 1990, 1992; Padgett, Mumford, Hynes & Carter, 1988), however, research suggests that increased knowledge does not necessarily lead to the desired changes in self-management behaviour, especially diet and exercise (Estey, Tan & Mann, 1990; Rubin, Peyrot & Saudek, 1991; Krug, Haire & Heady, 1991), and does not lead to improved metabolic control (Dunn & Turtle, 1988; Raz, Soskolne & Stein, 1988; Barth, Gosper, Jupp, Simons & Chisholm, 1990; Bahru & Abdulkadir, 1993; Wierenga, 1994). Additionally, PE that is controlling and directive may

adversely affect clients' metabolic control (Sweet, Piziak & Carpentier, 1993), an iatrogenic risk for poorer outcome that is clearly a concern.

There is evidence that when patients with chronic diseases are encouraged to take an active role in, and question, their care, that the process and outcome of treatment is enhanced (Greenfield, Kaplan, & Ware, 1988, Roter, 1987), and that this is also true for patients with diabetes (Anderson, Funnell, Barr, Dedrick & Davis, 1991; Sweet et al., 1993). Butler, Peters and Stott (1995), for example, suggest that individuals with diabetes are likely to achieve more progress if they are encouraged to participate and set their own specific targets for change themselves. This has resulted in a move towards more patient-centred, or patient empowerment, approaches to PE in diabetes, which enable patients to make informed decisions about their diabetes treatment and to be fully responsible members of the health-care team (Anderson et al., 1991). Furthermore, as well as PE approaches to diabetes developing over the last 10-15 years to include patient empowerment, participation and collaboration (Norris, Lau, Smith, Schmid & Engelgau, 2002), there has also been a move to include behaviour change counselling techniques, such as setting small achievable goals, the use of prompts, and feedback (Funnell & Haas, 1995).

Training health professionals in more patient-centred approaches appears to have positive effects on their attitudes towards patients with diabetes (Anderson et al., 1991; Williams, Freedman & Deci, 1998). Additionally, patients appear to benefit in terms of their perceived ability to communicate with their health care practitioner, treatment satisfaction, and emotional well-being (Kinmonth,

Woodcock, Griffin, Spiegel & Campbell, 1998). It is unclear, however, whether these more patient-centred approaches lead to improvements in diabetes outcome (Gonder-Frederick et al, 2002).

Earlier meta-analyses of diabetes PE (Padgett et al., 1988; Brown, 1988, 1990, 1992) suggest a moderate, positive effect size (ES), which tended to diminish over time. For example, Brown (1992) found an early moderate effect size of $d=.46$, which peaked at .91 one to six months post-intervention, and then declined after six months. These analyses also suggest that the effect size was greatest for knowledge, and least for self-management behaviour. Brown (1992) in a re-analysis of previous meta-analysis also found that the effect sizes for both knowledge and metabolic control was lowest for patients over 40 years of age (e.g., the 95% confidence interval for patients 55-68 years included a zero effect).

Recent meta-analyses of diabetes PE (Norris, et al., 2002; Gary, Genkinger, Guallar, Peyrot & Brancati, 2003), however, suggest clinically and statistically significant decreases in glycated haemoglobin (HbA1c) post-intervention, but these effects also tended to diminish over time. For example, Norris et al (2002) found that while there was a .76% decrease in HbA1c immediately post-intervention, but the effect declined to .26% from one month follow-up. As well as a concern about the need for interventions that demonstrate long term change, Gary et al (2003) also point out that even the short-term decreases in HbA1c achieved in these studies are not at the level (1-2% decrease) achieved with intensive medically-based interventions in the DCCT (DCCT Research Group, 1993) and the UKPDS (Turner et al, 1996; UKPDS Group, 1998).

Research in diabetes health practitioner-patient interaction suggests that patients' and practitioners' goals often differ (Armstrong, 1991; Marteau, Johnston, Baum & Bloch, 1987). Nevertheless, patients often test out the advice of health practitioners when provided with new information, and initial impressions of success or failure are often powerful influences on the patient's future behaviour (Drummond & Mason, 1990; Kelleher, 1988). Good continuity of care is also valued by patients and can positively influence blood glucose control (Kelleher, 1988; Mazzuca, 1983; Marteau & Kinmonth, 1988).

Research also suggests that there is considerable diversity in patients' acceptance and understanding of their diabetes (Armstrong, 1991; Drummond & Mason, 1990; Kelleher, 1988), and that patients' belief in the importance of metabolic control is often reflected in the level of metabolic control attained (Greenfield et al., 1988, Murphy, Kinmonth & Marteau, 1992). Additionally, when considering behaviour change, short-term comfort or security is often preferred over long-term health (Drummond & Mason, 1990).

A New Zealand survey (Simmons, Swan, Lillis & Haar, 2005) of barriers to diabetes care among medical, dietetic and nursing staff involved in the management of patients with diabetes found that 'motivation/denial', diabetes knowledge, and the lifestyle regimen were considered the top three barriers to diabetes care. Motivation was ranked first by those working in specialist diabetes services and General Practitioners (GPs).

Summing up, the evidence suggests that while PE may be an effective intervention for some individuals with diabetes, it may not be an effective intervention for all individuals with diabetes, or for an individual all of the time, with between and within individual variation in motivation for diabetes self-management. Thus, while PE may be an important component of diabetes care, there needs to be alternative approaches which include a focus on motivation for, or ambivalence about, behaviour change for those individuals who, while knowing what it is that they need to do to manage their diabetes, still struggle with diabetes self-management.

Psychological Interventions

Psychological interventions for diabetes, which typically comprise counselling or cognitive behaviour therapy (CBT) use the therapeutic alliance and/or skill-building to facilitate change in patients' cognitive, behavioural and emotional functioning (Ismail, Winkley & Rabe-Hesketh, 2003; Winkley, Landau, Eisler & Ismail, 2006). This is in contrast to PE which is based on didactic and enhanced learning methods (such as behaviour change counselling strategies) which aim to improve diabetes self-management through increasing knowledge (Ismail et al, 2003; Winkley et al., 2006). Thus, psychological interventions differ from educational interventions in their theoretical basis, the training and clinical skills required, and their implication for resources (Ismail et al, 2003; Winkley et al., 2006).

In meta-analyses of randomised controlled trials (RCTs) of psychological interventions to improve glycemic control, Ismail et al (2003) found that for patients with Type 2 diabetes HbA1c was lower (mean of .76%) following psychological

intervention compared to treatment as usual (TAU, which typically involves medical oversight and may include provision of information and advice), PE or control groups. In a similar meta-analysis Winkely et al (2006) found similar results for patients with Type 1 diabetes, with a mean reduction in HbA1c of .48% for children and adolescents, and a .22% decrease for adults. Both studies also found that psychological distress (e.g., depression, stress, binge-eating) was significantly lower following psychological intervention for patients with Type 2 diabetes ($ES = -.58$), and children and adolescents with Type 1 diabetes ($ES = -.46$), but not for adults with Type 1 diabetes ($ES = -.25$).

While these studies suggest that psychological interventions contribute to improved metabolic control and psychological well-being, they are typically provided by psychologists, sometimes in conjunction with other specialist staff (e.g., nurse educators, dietitians), and comprise five or more weekly sessions (Ismail et al, 2003; Winkley et al., 2006). As a result, the resource implications for such interventions limit the degree to which these can be adopted as routine treatment for diabetes. Thus, there is a need for brief interventions, which are individually tailored, and culturally sensitive (given the high rates of diabetes among indigenous peoples), which can be integrated into routine care (Clark & Hampson, 2001).

MI has been suggested as one such intervention (Carino, Coke & Gulanick, 2004; Lugoboni, Quaglio, Mezzelani, Pajusco, Casari, & Lechi, 2004; Doherty & Roberts, 2002; Stott et al., 1995; Stott, Rees, Rollnick, Pill & Hackett, 1996). MI would provide a means of working with patients with diabetes to help build and strengthen motivation, while at the same time providing a patient-centred approach

which would address many of the issues noted above. For example, MI with its emphasis on collaboration and agenda setting is likely to mean that the patient's and health practitioner's goals for treatment are similar. Additionally, MI is likely to include an exploration of the patient's health beliefs and personal models of diabetes, and to focus on building self-efficacy, all factors which have been found to be predictive of diabetes self-management. The next section in this chapter provides a review of MI.

Motivational Interviewing

MI is defined as "a directive, client-centred counselling style for eliciting behaviour change by helping clients explore and resolve ambivalence" (Rollnick & Miller, 1995, p.326). It evolved from Miller's experience with the treatment of problem drinkers, and when first described by Miller (1983) was more a style of therapy than a set of particular techniques (Miller, 1996).

Miller (1983) conceptualised motivation as a state of readiness for change, rather than a static personality-like trait or attribute. As a state, motivation may fluctuate over time or from one situation to another, and can be influenced to change in a particular direction. A lack of motivation, specifically a lack of motivation to change expressed as resistance to change, is not seen as inherently unchanging within an individual, but rather something that is variable and open to change. This conceptualisation of motivation as a state which is open to change, was in sharp contrast to traditional, and, at the time, current, approaches to the treatment of addictive behaviours, which saw motivation to change as a personality problem, and

denial as something that had to be dealt with through aggressive confrontation (Di Cicco, Unterberger & Mack, 1978; Johnson, 1973; Yablonsky, 1965, 1989). In fact, Miller and Rollnick (1991) later suggested that adopting an aggressive and/or confrontational style (as in traditional approaches) is likely to produce responses from a client (such as arguing) which may then be interpreted by the therapist as denial or resistance, thus, creating a "self-fulfilling prophecy" (p.10).

Principles And Techniques

Rollnick and Miller (1995, p.326) distinguish between the "spirit" of MI and specific MI techniques. Within the spirit of MI, readiness to change is not seen as a client trait, but a "fluctuating product of interpersonal interaction" (Rollnick & Miller, 1995, p.327), and motivation to change is viewed as something which is evoked in the client, rather than imposed. It is the individual's task (not the therapist's) to articulate and resolve his or her own ambivalence. It is the therapist's task to expect and recognise ambivalence, and to be directive in helping the client to examine and resolve his or her ambivalence. This distinction between the "spirit" of MI and its techniques is important. It is possible for a therapist to apply the techniques of MI without holding to the "spirit" of MI (e.g., the therapist's aim is to manipulate the client into agreeing to change). This, however, would not be MI, and is likely to elicit resistance, and therefore have reduced efficacy.

An empathic style (Rogers 1957, 1959), which is known to be the key component to effective brief interventions (Miller, Taylor & West, 1980; Valle, 1981), is fundamental to MI, with the underlying attitude being one of acceptance, and belief

that ambivalence is normal. Within this empathic style it is the therapist's task to create and amplify any discrepancy between the client's present behaviour and important goals, thereby creating cognitive dissonance (Draycott & Dabbs, 1998; Festinger, 1957), so that the client him or herself presents the argument(s) for change. Without a supportive/empathic style the therapist is unlikely to be able to explore the client's ambivalence without eliciting resistance (Patterson & Forgatch, 1985).

Resistance, if it is encountered, is a signal to change strategy, rather than oppose the resistance. Argumentation or direct persuasion are considered counterproductive and should be avoided, as they are likely to produce defensiveness or further resistance. Instead, resistance is acknowledged and explored, using a quiet and facilitative style, within a relationship that is more like a partnership than an expert/recipient role, with the view to shifting the client's perceptions. This change in perception of resistance as something that is not bad, but is to be expected, and which should not be challenged, but be seen as a signal to shift strategies, is likely to contribute to clinicians' reports (van Bilsen, 1996) that they find working with difficult patients more enjoyable when using MI. This should lead to increased clinician self-efficacy (Bandura, 1977a), and may also contribute to increases in client self-efficacy.

Because client self-efficacy is a general predictor of therapy outcome (Bandura, 1977b, 1982), MI aims to support self-efficacy by seeing the client as a valuable resource in finding solutions to problems. While the client is seen as responsible for choosing and carrying out personal change, MI also acknowledges that, at the same time, the client must have a belief in their ability to change. That is,

without a belief that change is possible change is unlikely to happen. Within MI it is recommended that the therapist also focuses on increasing the client's belief in his or her ability to change (e.g., by identifying and acknowledging successful behaviour change in the past).

Rollnick and Miller (1995) describe specific, trainable therapist behaviours (techniques), which are characteristic of MI. Seeking to understand the client's frame of reference, particularly via reflective listening, and expressing acceptance and affirmation are techniques of MI borrowed from Roger's (1957, 1959) non-directive client-centred therapy. Going beyond this, the MI techniques of eliciting and selectively reinforcing the client's own self-motivational statements, monitoring the client's readiness to change, ensuring that resistance is not generated by jumping ahead of the client, and affirming the client's freedom of choice and self-determination, are techniques which distinguish MI from other client-centred therapies (Miller & Rollnick, 1991).

These techniques are applied within the context of the ingredients for effective brief interventions, using the acronym FRAMES (Miller & Rollnick, 1991; Miller & Sanchez, 1994). The acronym FRAMES stands for Feedback, Responsibility for change lies within the individual, Advice-giving, Menu of change options, Empathic style, Self-efficacy is enhanced. In MI, however, advice is not given without the individual's permission and, when given, is accompanied by actively encouraging the person to make his or her own choices.

Theoretical Basis and Historical Development of MI

MI was not based on any specific theory. Rather, Miller (1983) drew from social psychology, applying theories about: (1) attribution (Kopel and Arkowitz, 1975) i.e., self-attribution of behaviour change increases the likelihood of maintenance of that change; (2) cognitive dissonance (Festinger, 1957) i.e., if a person knows various things that are not psychologically consistent (dissonant) with one another, he/she will, in a variety of ways (e.g., behavioural or cognitive change), try to make them more consistent; (3) self-perception theory (Bem, 1967) i.e., inferences arising from self-observation of one's own behaviour may affect subsequent behaviour, attitudes and beliefs; (4) and self-efficacy (Bandura, 1977a, 1977b, 1982) i.e., expectations of personal self-efficacy determine whether behaviour change will be initiated, how much effort will be expended, and how long it will be sustained in the face of obstacles or aversive experiences; and also drew on empathic processes from the methods of Rogers (1957, 1959).

Despite the initial lack of empirical data, considerable interest was shown in MI after Miller's initial (1983) article. This was perhaps because MI offered a new way of approaching substance abuse problems, which provided hope for working with individuals who were previously viewed as unmotivated or resistant, and therefore untreatable, or at best difficult to treat. More recently, interest in MI may also have been maintained because it is consistent, at least in superficial ways, with postmodernist paradigms, emphasising collaboration and client empowerment (Gerber & Basham, 1999).

Because of this interest, Miller began to research the processes and outcomes of MI, and as a result his initial model was elaborated by Miller and Rollnick (1991), and developed further in 1995 (Rollnick & Miller, 1995), with further refinements (e.g., the notion of importance and confidence) in 2002 (Miller & Rollnick, 2002). A major development was to link MI to the transtheoretical model (TTM) of change (Prochaska & DiClemente, 1982; Prochaska, DiClemente & Norcross, 1992), which was developed in parallel with MI (Rollnick & Morgan, 1996). The TTM describes a series of stages which people pass in the course of changing their behaviour. The stages consist of *pre-contemplation*, at which time the person has not contemplated having a problem or needing to change; *contemplation* which is characterised by ambivalence about change, with the person oscillating between concern and unconcern; *determination* or *preparation* when the person appears to have made a decision to change and are on the verge of taking action towards behaviour change; *action* during which the person engages in behaviour to bring about change; and *maintenance* in which the challenge is to maintain the behaviour change and prevent relapse. The TTM can therefore be seen as providing a framework for understanding the change process itself, and MI as providing a means of facilitating this change process (Sobell, Toneatto & Sobell, 1994).

Within the TTM of change, readiness for change is seen as the extent to which the individual has contemplated the need for change, and reached a decision balance between the pros and cons of change. Lack of motivation can therefore be viewed as a "perceptual" (Miller, 1994, p.115) problem, in which the individual sees no (or insufficient) need to change, whereas others (e.g., helping professionals, family) do perceive a problem and a need for change.

MI aims to alter how the client sees, feels about, and means to respond to, the problematic behaviour. The therapist's response to ambivalence is the key to this. The ambivalence is resolved by focusing on the client's wants, expectations, beliefs, fears and hopes, with particular emphasis on the inconsistencies between these and the problematic behaviour.

Despite Miller (1983) having drawn upon cognitive dissonance theory in developing MI, several aspects of dissonance theory are not used in MI, and the inclusion of these may improve the effectiveness of MI (Draycott and Dabbs, 1998). In particular, Draycott and Dabbs (1998) suggest that more attention be given to optimal methods for arousing and maintaining dissonance. They suggest keeping a visual record to keep the inconsistencies salient, and generating a decision balance sheet (for and against change) early in the session, which then becomes the focus for discussion so that cognitions consistent with not making change are removed or reduced in importance, using MI techniques, while the importance of cognitions supporting change is increased. They also suggest a greater structure to the way MI is delivered, so that the focus is on "invoking and channelling dissonance" (p.362), with a greater emphasis on eliciting and exploring cognitions, as in standard cognitive therapy (Beck, 1995). That is, the therapist should initially establish the client's cognitions about the problematic behaviour, so as to assess their current dissonance. Following this, the cognitions should be explored in order to reduce the importance of cognitions consistent with the problematic behaviour and to increase the importance of inconsistent cognitions, while reinforcing statements which recognise dissonance, and implying and reinforcing the option of behaviour change. The therapist, however, should take care not to over-structure MI sessions, as this may result in the

sessions being therapist driven, rather than client-focused, which in turn may produce resistance and thereby reduce efficacy.

Draycott and Dabbs (1998) further suggest that the use of responses other than a commitment to behaviour change can be discouraged by the therapist implying the response of behaviour change as soon as possible after dissonance is recognised, thereby increasing the probability of this response being adopted. This suggestion, however, is at risk of being at odds with the 'spirit' of MI. In implying the response of behaviour change (particularly if this is done early on), the therapist would have to be careful that he/she is not perceived as imposing the notion of behaviour change on the individual. The therapist must also take care that by doing so before the client is ready for change, he/she does not elicit resistant responses.

Miller and Rollnick (1991) compare MI with skills training approaches, such as CBT, implying that these are two contrasting therapies, with CBT being “highly prescriptive, offering specific directions, instructions, and assignments” (p.54). There appears, however, to be considerable overlap between MI and CBT, with CBT encompassing the ingredients Miller and Rollnick (1991) identified as necessary for effective brief interventions (i.e., FRAMES), and both MI and CBT seek to elicit and explore the client’s thoughts and feelings, with the view to ultimately effecting behaviour change.

In both MI and CBT collaboration between the therapist and client is seen as crucial, with the therapist encouraging the client as much as possible to take an active role during the session so that they function as a team (Beck, Rush, Shaw & Emery,

1979). Furthermore, CBT techniques of guided discovery (Beck et al., 1979) and Socratic questioning (Overholser, 1993), which aim to explore the client's problems and help the client draw his or her own conclusions by examining the evidence, considering alternatives, and weighing advantages and disadvantages, and the use of a graded series of questions, appear to fit well with MI's reflective listening, which seeks to understand the client's frame of reference. Thus, it would appear that MI and CBT have much in common, the essential difference being that MI focuses on establishing whether the client is ready for change by being in the contemplation of preparation stage of change, in a way that is likely to increase the client's readiness for change, whereas CBT assumes that the client is ready for change (i.e., in the action stage).

Process of Change

There is growing evidence supporting propositions made from MI theory. For example, MI theory posits that MI will increase client change talk and minimise resistance, and that the extent to which clients verbally defend the problematic behaviour (i.e., resistance) will be inversely related to behaviour change. Miller, Benefield and Tonigan (1993) found that problem drinkers randomly assigned to MI showed 111% more change talk. In contrast, problem drinkers randomly assigned to a confront/direct intervention showed 78% more resistance than those receiving MI. Furthermore, level of resistance during intervention predicted poor outcome (i.e., lack of improvement in drinking behaviour). These findings have been further supported through psycholinguistic analysis of MI (Amrhein, Miller, Yahne, Palmer & Fulcher, 2003) which showed robust, atypical increases in change talk and decreases in

commitment to drug use during MI, with verbal commitment to drug use during MI predicting continued drug use.

MI theory also posits that the extent to which clients verbally argue for change (i.e., change talk) will be directly related to behaviour change. This proposition, however, has not been supported, with the frequency of change talk found not to be predictive of behaviour change (Miller et al, 1993; Miller, Yahne & Tonigan, 2003). Amrhein et al (2003) suggest that change talk itself is too global a concept, and that instead there are natural markers of readiness to change, which involve the client expressing a desire, ability, reasons, need and commitment to change, and that what is important is not just the frequency, but rather the strength with which these are expressed, with the most predictive client speech occurring at the end of the session.

MI theory further posits that the resolution of ambivalence about behaviour change is promoted by accurate empathy. Research again supports this proposition, with therapist empathy and Rogerian skill found to be predictive of client outcome both in MI (Miller et al., 1980) and more generally in psychotherapy (Valle, 1981). MI theory posits that the resolution of ambivalence in a particular direction is influenced by the clinician's differential reinforcement of client speech. This is supported by Sellman, Sullivan, Dore, Adamson and MacEwan (2001) who found that MI produced superior outcomes to a non-directive patient-centred intervention. This finding suggests that what facilitates behaviour change in MI is its focus on eliciting, and using reflective listening to selectively reinforce, client change talk, rather than it simply being a patient-centred intervention.

Specific MI Interventions

The principles of MI were incorporated into a brief intervention, called the Drinker's Check-up (DCU) for problem drinkers (Miller, Sovereign & Krege, 1988; Miller & Sovereign, 1989), which is an assessment-based strategy, involving a comprehensive assessment of the client's drinking and related behaviours, followed by systematic feedback to the client of the findings using a MI communication style. The DCU was extended into a four session form of MI by Miller, Zwedben, DiClemente and Rychtarik (1992) as one of three interventions for alcohol abuse and dependence evaluated in Project MATCH (1993) and called MET. MET aims to motivate clients to make changes, rather than provide step-by-step advice about behaviour change.

Additionally, a set (menu) of techniques, which follow the spirit and practice of MI, called Brief MI have been developed for use in a single 40 minute session in primary care settings, with non-help seeking problem drinkers (Rollnick, Heather & Bell, 1992). Further studies are currently evaluating whether the spirit of MI can be captured in even briefer (e.g., 5-10min) encounters (Stott, Rollnick, Rees & Pill, 1995).

MI has been provided by telephone consultation (Ludman, Curry, Meyer & Taplin, 1999), and in a group format (Ingersoll & Wagner, 1997; Van Horn & Bux Jr, 2001; Lincourt, Kuettel & Bombardier, 2002). A group format, while more efficient, may compromise the effectiveness of MI as the intervention will not be able to be targeted at each individual's specific needs as it is likely that different members of the

group will be at different stages of change, at different times during the group sessions. Studies are also currently underway exploring other formats for MI, such as computerised or paper self-help manuals.

Areas of application

MI has been used in a variety of settings. This includes inpatient (Kemp et al., 1998; Long & Hollin, 1995; Swanson et al., 1999), and outpatient (Aubrey, 1998; Bien, Miller & Boroughs, 1993) settings, general hospital ward (Heather, Rollnick, Bell & Richmond, 1996) and emergency department (Monti, et al., 1999); general medical practice (Rollnick et al., 1992; Rollnick, Kinnersley & Stott, 1997), and the home (Tappin et al., 2000).

Similarly, MI has been used with a variety of different populations, including offenders on probation (Harper & Hardy, 2000); pregnant women (Handmaker, Miller & Manicke, 1999); patients with traumatic brain injury (Bombardier & Rimmele, 1999); couples (Crous, 1998, Zweben, 1991); and families (Rao, 1999). Several studies (Berg-Smith et al., 1999; Colby et al., 1998; Lawendowski, 1998; Tober, 1991) also report on the use of MI with adolescents, for whom MI may be particularly suited because of its emphasis on personal responsibility and avoidance of an authoritarian stance.

MI has also been applied in a number of countries, with Miller and Rollnick (1991) citing examples of the application of MI in Australia, England, The Netherlands, Scotland, and the United States. Additionally, it appears likely that MI,

with its non-authoritarian stance and emphasis on personal choice, is likely to be acceptable to indigenous peoples and ethnic minority groups who seek self-determination and self-empowerment. Longshore, Grills and Annon (1999), for example, have included MI in a "culturally congruent" (p.1223) intervention for African Americans, stating that MI's emphasis on personal choice, and avoidance of advice-giving and confrontation as reasons why MI was a culturally congruent approach.

Additionally, MI has been applied to a variety of problems. As well as being used as an intervention for alcohol abuse (Heather et al., 1996; Miller et al. , 1988; Miller, Benefield & Tonigan, 1993; Project Match Research Group, 1993; Sellman et al., 2001) MI has been applied the treatment of abuse of other substances, such as heroin (Saunders, Wilkinson & Allsop, 1991; Saunders, Wilkinson & Phillips, 1995; Van Bilsen, 1991; Van Bilsen & Whitehead, 1994), cocaine (Stotts, Schmitz, Rhoades & Grabowski, 2001), and marijuana (Stephens, Roffman & Curtin, 2000), as well as with substance abusers with dual diagnoses (Martino, Carroll, O'Malley & Rounsaville, 2000; Swanson, Pantalon & Cohen, 1999). It has been suggested that MI may be of particular use with individuals dually diagnosed with schizophrenia and substance abuse, who are less able to benefit from confrontational methods typical of traditional substance abuse treatment (Bellack & DiClemente, 1999; Carey, 1996), and that MI, with its brevity and focus on initiating behaviour change, could readily be incorporated into acute inpatient settings (Van Horn & Bux Jr, 2001).

MI also appears to hold considerable promise as an adjunct to skills based treatments such as CBT or Behaviour Therapy (BT). Baer, Kivlahan and Donovan (1999) suggest that the motivational strategies of MI could be usefully integrated with the skills training of CBT so that therapy includes the assessment and support of both why the client wants change (motivation) and how change can be achieved (skills). MI, then, can be seen as a means of assessing a client's readiness for change and preparing him/her for change by resolving any ambivalence as it arises, either at the beginning of treatment or through the treatment process. On the other hand, the skills based treatment (i.e., CBT or BT) can be seen as a means of increasing the client's confidence and ability to change.

This integration of MI and CBT or BT appears to be occurring in clinical practice (Allsop & Saunders, 1991; Kent, 1991), however, studies evaluating the effectiveness of MI combined with CBT (Barrowclough et al., 2001; Kemp, Kirov, Hayward and David, 1998) or BT (Long & Hollin, 1995; Van Bilsen & Whitehead, 1994) only report the overall effectiveness of the combined intervention in contrast to a control condition. This means that it is not possible to evaluate the relative efficacy of each component or the efficacy of the combined treatment compared to each intervention alone (e.g., the efficacy of MI + CBT compared to either MI or CBT).

MI has also been applied to problems such as sexual offending (Mann & Rollnick, 1996), conflict over child access (Crous, 1998), attendance at group counselling for domestic abusers (Taft, Murphy, Elliott & Keaser, 2001), and as an intervention for at-risk couples (Cordova, Warren & Gee, 2001) and families (Rao, 1999). Additionally, there has been increasing interest in the use of MI in the

treatment of anorexia nervosa and bulimia nervosa, with the recognition that ambivalence about treatment is common with eating disorders (Treasure, Katzman, Schmidt, Troop, Todd & de Silva, 1999; Feld, Woodside, Kaplan, Olmsted & Carter, 2001). These tend to be isolated pilot studies, using quasi-experimental designs (mostly non-equivalent control group design), but together they provide support for the potential application of MI to a wide range of problems.

Health Behaviour Change. There has been increasing interest in the application of MI to managing chronic illness and health behaviour change (Rollnick et al., 1992; Rollnick, 1996; Rollnick, Mason & Butler, 1999). This includes pain management (Jensen, 1996), cardiac rehabilitation (McHugh et al., 2001; Brodie & Inoue, 2005), and health behaviour change, such as that required for the prevention and management of human immunodeficiency virus (Foley et al., 2005; Golin et al., 2006), smoking cessation (Emmons et al., 2001; Valanis et al., 2001), physical activity (Harland et al., 1999; van Vilsteren, de Greef & Huisman, 2005; de Blok et al., 2006), adherence to asthma medication (Schmaling, Blume & Afari, 2001), lifestyle change for hypertension (Woollard et al., 1995), dietary change for hyperlipidaemia (Mhurchu, Margetts & Speller, 1998; Kreman et al., 2006), and daily fruit and vegetable intake (Resnicow et al., 2001). These studies included uncontrolled/non-experimental designs, quasi-experimental designs with non-equivalent control groups, and RCTs (mostly small pilot studies). Taken together, the results provide support for the potential application of MI to a wide range of health problems, with MI performing better than no treatment, but significant differences were not always achieved when MI was compared to another active treatment (such as advice about and support for health behaviour change).

Traditionally, health practitioners have encouraged patients to make changes through the provision of advice (i.e., information giving with direct persuasion) about behaviour change (Tuckett, Boulton, Olsen, & Williams, 1985). While this works with some patients (Wallace, Cutler & Haines, 1988), the evidence of the effectiveness of advice giving about lifestyle change is not strong (Rollnick et al., 1992), with success rates of only 5-10% (Kottke, Battisa, Degriese & Brekke, 1988; Bien, Miller & Tolligan, 1993).

Furthermore, there is evidence that patients do not necessarily want advice if it is provided in a style that is perceived as being "told what to do" (Stott & Pill, 1990). Additionally, advice giving can develop into non-constructive disagreement, with the health practitioner placing emphasis on the benefits of change while undervaluing the personal costs, and the patient looking closely at the personal implications of change and the immediate costs while minimising future benefits (Tuckett et al., 1985). The risk of such an encounter is that the patient becomes resistant to change or resistance, if already present, is enhanced (Miller & Rollnick, 1991).

In contrast, there is evidence that more patient-centred approaches to health/lifestyle change produce better outcomes (Kaplan, Greenfield & Ware, 1989; Stewart & Roter, 1989). The essential features of these patient-centred approaches are that the patient does most of the talking, and that there is a 'meeting between experts' (Tuckett et al., 1985), with the concept of reciprocity in the consultation (Roter, 1987). Patient-centred counselling, however, has not been developed into a replicable method specifically geared towards negotiating behaviour change in health consultations (Rollnick, 1996).

MI appears consistent with a number of models of health behaviour, such as Locus of Control (Rotter, 1966), the Health Belief Model (Becker, 1974), the Theory of Reasoned Action (Fishbein & Azjen, 1975), Social Cognitive Theory (Bandura, 1977b), Decisional Balance (Janis & Mann, 1977), the Health Action Process Model (Schwarzer, 1992), the Self-Regulatory Model (Leventhal, Diefenbach & Leventhal, 1992), and Self-Determination Theory (Deci, Eghrari, Patrick & Leone, 1994). All of these models, despite differences in their terms and emphasis, share three common constructs (Doherty et al., 2000), which are the focus of MI. These are (1) the patient's expectations about the consequences of engaging in the behaviour; (2) the influence of the patient's perception of, or beliefs about, personal control over the behaviour; and (3) the social context of the behaviour.

The Health Belief Model (HBM), for example, suggests that health behaviour change depends on the simultaneous occurrence of, first, the belief that one is susceptible to a health threat or the medical or social consequences of the health threat; second, sufficient health concern is felt to make the issues relevant; and third, the belief that a particular health recommendation would be beneficial in reducing the perceived threat at an acceptable cost (Rosenstock, 1974). MI appears to be a process by which the preceding three factors for health behaviour change, as postulated by the HBM, can be created or enhanced in the patient by the health practitioner. Additionally, it has been suggested (Rosenstock, Stretcher & Becker, 1988) that the HBM could be improved by drawing upon Bandura's self-efficacy theory (Bandura, 1977a). According to this theory, the degree to which an individual develops the expectancy that they will be able to perform desired behaviours (i.e., self-efficacy) is an important factor in behaviour change (Bandura, 1977a).

Self-efficacy has been used to predict health behaviour such as smoking cessation, weight reduction, exercise, and cardiac rehabilitation (Fluery, 1992). As mentioned earlier, self-efficacy is an important aspect in MI, with MI attempting to increase the patient's belief in his or her ability to change his or her behaviour.

MI, therefore, appears to hold substantial promise for health behaviour change. It is consistent with the call (from patients, and health researchers and practitioners alike) for more patient-centred approaches in health care in which the health practitioner-patient relationship is a partnership, rather than an expert-recipient one. MI also provides health practitioners with a means of tailoring their interventions to suit the patient's degree of readiness for change. In particular it provides practitioners with an effective means of working with patients who are ambivalent about, or not ready for, change.

Despite the promise which MI holds for promoting health behaviour change, there are few controlled studies evaluating the efficacy of MI with health problems, with clinical innovation remaining ahead of scientific evaluation (Rollnick, 1996). The challenge is to develop MI interventions that are useable in health consultations (which tend to be brief), are trainable, and are sufficiently specific to enable proper evaluation (Rollnick et al., 1992). With such interventions patients are likely to feel listened to and understood by their health practitioner. Health practitioners, on the other hand, are likely to gain a greater sense of achievement from recognising change in patients' readiness as important progress, rather than seeing concrete behaviour change as the only goal. Thus, the resulting MI interventions are likely to contribute

to a greater sense of satisfaction for patients and practitioners, as well as helping promote health behaviour change.

In particular, MI appears to be potentially useful for promoting chronic disease management, such as diabetes self-management. Many of these diseases in both etiology and treatment are related to lifestyle factors such as diet, exercise, and smoking, but changing and maintaining such behaviours is difficult, requiring time and considerable effort and motivation, and ambivalence about behaviour change is a common problem (Rollnick, et al., 1992).

Empirical Support

Reviews and meta-analyses. The number of MI publications and MI outcome studies has risen exponentially since its development in the mid-late 1980s, with the MI website (www.motivationalinterview.org) citing over 400 publications in 2003 and nearly 70 outcome trials in 2004. Since 2001 a number of systematic reviews and meta-analyses of MI have been published.

The first of these (Dunn, Deroo & Rivara, 2001) was conducted ‘out of concern that the popularity of MI had outstripped the evidence for its effectiveness’ (p.1726). This involved a systematic review of 29 RCTs evaluating MI across four behavioural domains - substance abuse (n=27), smoking (n=2), HIV risk (n=4), and diet/exercise (n=6), of which 26 studies reported adequate information to calculate the effect size. The most cumulative evidence for the effectiveness of MI was found for substance abuse, particularly when MI was used as an enhancement to more intensive

treatment, with significant effect sizes reported in 73% (11 out of 15) studies. Data, however, were inadequate to draw conclusions regarding the effect of MI in the other domains.

In a meta-analysis of 30 controlled trials of MI (i.e., alcohol problems $n=15$, smoking $n=2$, drug abuse $n=5$, HIV risk $n=2$, diet/exercise $n=4$, and treatment compliance $n=1$) Burke, Arkowitz and Menchola (2003) found that MI was equivalent to other active treatments, such as CBT. Moderate effects were also found when MI was compared to no treatment and/or placebo for alcohol problems ($ES=.25$ to $.53$), drug addiction ($ES=.56$), and diet/exercise ($ES=.53$), but there was no effect for smoking and HIV risk. They also found that higher doses of MI (i.e., more than 60 minutes of MI) yielded a greater effect size, and the effects of MI did not fade significantly over time, with follow-up periods ranging from four weeks to four years (mean=18 weeks). Burke et al (2003) conclude with the recommendation that future outcome research includes careful description of the training involved and an evaluation of treatment integrity, and call for more process studies in order to assist with understanding the links between the process and outcomes of MI.

Burke, Dunn, Atkins and Phelps (2004) enlarged on the studies used by Burke et al (2003) with a meta-analysis of 38 controlled trials of MI (alcohol problems $n=20$, drug abuse $n=6$, smoking $n=2$, HIV risk $n=2$, diet/exercise $n=4$, and $n=1$ for treatment compliance, eating disorders, asthma, and injury-risk behaviour), and again found a moderate effect sizes for MI for alcohol abuse ($ES=.35$ to $.53$), drug abuse ($ES=.56$) and diet/exercise ($ES=.53$), and no effect for smoking and HIV risk behaviour. Additionally, following on from the recommendations of Burke et al (2003) for an

increased understanding of the process of change in MI, they reviewed research in which the process of MI was examined. This research suggested that MI did not differentially increase readiness to change in comparison to other active interventions, and that it was not yet known whether feedback, MI per se, or the combination was essential for an effect, but that challenging or disagreeing by clients produced poorer outcomes. They concluded that controlled studies demonstrate that MI is consistently efficacious for substance abuse problems, and has the potential in other problem areas, such as medical treatment compliance and health behaviour change, but that the evidence for efficacy in these areas is not yet sufficient.

Following on from this Rubak, Sandbeck, Lauritzen and Christensen (2005) performed a meta-analysis of 72 RCTs of MI in the treatment of disease (i.e., diabetes/asthma $n=2$, smoking $n=8$, diet/exercise $n=8$, alcohol abuse $n=23$, psychiatry/drug addiction $n=12$), finding a positive effect for MI in three out of four studies (including studies involving the treatment of diabetes, asthma, and weight). Only 46% of studies, however, used direct health outcome measures, with a positive effect obtained in 75% of these studies, although no effect was obtained for HbA1c and there was only a very small, non-clinically significant negative effect for total cholesterol. They also found, similar to Burke et al (2003), a dose effect, with more than one session of MI producing greater effect, and the longer the follow-up the increased likelihood of finding an effect. For example 36% of studies with a 3-month follow-up showed a positive effect compared to 81% of studies with a 12-month or longer follow-up. Also similar to Burke et al (2003, 2004), they recommend that future MI research more clearly describe the MI training and evaluates treatment integrity, but they also recommend that future research use a combination of direct

(i.e., health outcome) and indirect measures (i.e., health behaviour), and that MI be evaluated in clinical settings.

In another meta-analysis of 72 studies, Hettema, Steele and Miller (2005) found that there was wide variability in effect sizes across studies, and within problem areas (e.g., effect size of 0 to 3.0 for alcohol problems). Just under half ($n=31$) of the studies in this analysis were from the alcohol treatment area, but the analysis also comprised studies reflecting the wide range of applications of MI, including MI applied to treatment compliance ($n=5$), and diet/exercise ($n=4$). They also found that the effects of MI tended to appear early, with the exception of certain problem areas or dependent measures (e.g., diet and exercise) where effects tended to be delayed.

Hettema et al (2005) also found that the effect size did not differ with the professional background of the MI practitioner, suggesting that a variety of health practitioners, as well as para-professionals may effectively practice MI. They did, however, find that the effect size was reduced by the use of a manual to guide MI (from .65 for studies not using a manual to .37 for studies using a manual). This lessening of an effect for manually guided MI may reflect the importance of MI being client-centred, with the focus being on using particular MI strategies to match the clients' readiness for change. A manual, if too prescriptive, or if used in a prescriptive way, may reduce the efficacy of MI, hence the above finding. They also found that only 29% of studies comprised post-training supervision and only 36% of studies measured treatment integrity. Additionally, Hettema et al (2005) found that the effect size was higher for ethnic minority groups ($ES=.79$) compared to Caucasians ($ES=.39$). This finding is consistent with Longshore et al's (1999) finding

that MI was a culturally congruent intervention for African Americans, and suggests that MI may be an example of good cross-cultural counselling.

The most recent systematic review (Knight, McGowan, Dickens & Bundy, 2006) evaluated the effectiveness of MI in physical health care settings only. This comprised a review of eight controlled studies in the areas of diabetes (n=3), asthma (n=1), hyperlipidaemia (n=1), hypertension (n=1), and cardiology (n=2). While the strength of conclusions that can be drawn from these studies is limited by the small sample sizes, lack of power, and lack of validated measures, Knight et al (2006) found that most of the studies did show positive effects.

Empirical studies of MI applied to diabetes. There has been increased interest in MI as a means of promoting treatment adherence in diabetes (Carino, Coke & Gulanick, 2004; Lugoboni, Quaglio, Mezzelani, Pajusco, Casari, & Lechi, 2004; Doherty & Roberts, 2002; Stott et al., 1995; Stott, Rees, Rollnick, Pill & Hackett, 1996). There are, however, only a few outcomes studies.

Smith, Heckemeyer, Kratt and Mason (1997) in a randomised control pilot study investigated whether the addition of three MI sessions (conducted by psychologists) to a standard (16 week) behavioural weight reduction program for 22 obese women with Type 2 diabetes would increase adherence to treatment and improve glucose control. It was found that the group receiving MI attended more sessions, completed more food diaries, recorded their blood glucose level more often, and had better blood glucose control than the group receiving standard treatment.

Although both groups lost weight, there were, however, no differences between the two groups in the amount of weight reduction.

The effectiveness of Brief MI (i.e., one 30mins session of MI) for patients (aged 40-70 years) with Type 2 diabetes was evaluated in a RCT (Clark & Hampson, 2001; Clark, Hampson, Avery & Simpson, 2004), in which participants (n=100) were randomised to either TAU or Brief MI provided by one of the researchers. In addition to the Brief MI session, participants in the intervention group also received three 10 minute follow-up phone calls at one, three and seven weeks post-intervention, and two extra follow-up sessions at weeks 12 and 24. Measures (pre- and post-treatment, and 12-month follow-up) included self-report questionnaires regarding diabetes self-management (Summary of Diabetes Self-Care Activities Questionnaire – SDSCAQ), fat-related dietary behaviour (Kristal Food Habits Questionnaire and the Block Fat Screener), physical activity (Physical Activity Scale for the Elderly), body mass index (BMI), waist circumference, and metabolic measures (i.e., total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, HbA1c). The results indicated that there was a significant reduction in fat intake by the intervention group, which reflected in the objective data, with weight maintenance and a significant reduction in waist circumference in the intervention group compared to the control group, which were maintained or enhanced over 12-month follow-up. These changes, however, did not contribute to significant improvements in the metabolic (diabetes outcome) measures. These results, however, need to be interpreted with caution as the observed changes may be attributable to the increased contact (i.e., three 10 minute follow-up phone calls at one, and two extra follow-up sessions) rather than MI per se. Clark,

Hampson, Avery and Simpson (2004) conclude with a call for more research of MI in real world conditions, and with less motivated patients.

Viner, Christie, Taylor and Hay (2003) in a non-randomised pilot study compared a group intervention for adolescents (n=21, aged 11-17 years) with Type 1 diabetes with a control group (n=20 randomly selected patients who opted not to participate in the intervention group). The authors described the group (six weekly sessions) as a MI plus solution-focused therapy (SFT) group, but it also contained elements of CBT. 'SFT works with the client to identify what they already do well rather than focusing on which is going wrong, e.g., identifying "what helped" during periods when their diabetes was under control' (Viner et al., 2003 p.740). The results indicate that, compared to the control group, there was a significant decrease (i.e., 1.5%) in HbA1c at 4-6 months follow-up for the intervention group, which was partly (1.3%) maintained at 7-12 months follow-up, although the difference between the groups was not significant. It is again, however, unclear if the observed improvements were due to the intervention itself, or simply resulted from the increased contact the intervention group received. Additionally, it is unclear which elements of the group (e.g., MI, SFT or CBT) were the effective ingredients, and the authors do not state who provided the intervention and what training was required.

Another group intervention, comprising MI and externalising conversations (a component of narrative therapy which allows the individual to separate the problem from the person, by personifying the problem and relating to it as an external entity to the person), for adolescents (13-16 years) with Type 1 diabetes was evaluated by Knight et al (2003). In this RCT participants (n=40) were randomised to receive

either the intervention (run by a senior registrar in child psychiatry and a community psychiatry nurse) or TAU. Diabetes outcome and self-management data were not collected. Instead, the outcome measures comprised qualitative analysis of participants responses to open questions regarding their perceptions of their diabetes. The results suggest that, compared to the control group, the intervention group shifted their perceptions of diabetes, such that they reported feeling less threatened by, and more in control of their diabetes, were more accepting of their diabetes and felt less restricted by it. The authors argue that these findings are significant given previous research which suggests that adaptive shifts in illness perception are a determinant of adaptive outcome in chronic illness (Petrie & Wienman, 1997) and engagement in self-care (Hampson, Glasgow & Foster, 1995). Unfortunately, however, they do not provide data to support that these changes in illness perceptions did indeed translate to changes in diabetes self-management behaviour or outcome. Additionally, it is again unclear which elements of the group (e.g., MI or the externalising conversations) contributed to the changes observed.

Another pilot study (Channon, Huws-Thomas, Gregory & Rollnick, 2005; Channon, Smith & Gregory, 2005), evaluated the effectiveness of MI with adolescents (aged 14-18 years) with Type 1 diabetes. Participants were selected based on their responses to the Readiness to Change Questionnaire (RCQ - based on the TTM of change), with those with responses indicating that they were in the contemplation, preparation and action stage of change being included in the research. MI sessions were conducted by one of the researchers over six months, with the frequency (total number of sessions ranging from 1 to 9, with a mean of 4.7) as well as the presence of others (e.g., parents or partners) determined by each participant.

Self-report questionnaire data of health (Wellbeing Questionnaire), diabetes knowledge (Diabetes Knowledge Test - DKT), self-management behaviour (SDSCAQ), beliefs about diabetes (Personal Models of Diabetes Questionnaire – PMDQ), and family functioning and behaviour (Family Adaptability and Cohesion Evaluation Scales, and Diabetes Family Behaviour Scale) were collected pre- and post-intervention. Additionally, HbA1c data were collected before, during and after the intervention. The results suggest a significant decrease in HbA1c both during (i.e., 1.1%) and after (i.e., 0.8%) MI. In contrast, there was no significant change in HbA1c in a comparison group comprising 25 patients who declined to participate in the MI and those that were excluded from the study because they were classed as being in the maintenance stage of change on the RCQ. There was no significant change in the psychosocial measures of well-being, diabetes self-care, family behaviour and process, or diabetes knowledge. Yet, there was a significant decrease in their scores on the PMDQ, suggesting that diabetes was easier to live with. There was also a change in responses to the RCQ for 39% of participants, of which 64% indicated a movement towards action, but 27% also indicated a decrease in readiness to change. These results, however, need to be treated with caution due to the small number of participants, and the potential for the effect to have arisen from the placebo effect of regular contact rather than the MI itself. The authors also point out the inconsistency in the results, with questionnaire data indicating that there was no change in diabetes self-management behaviour, yet there were improvements in HbA1c. Consequently, they suggest that future research includes more intensive assessment of change and self-management behaviour.

In the largest RCT (n=265) of MI to-date, Rubak (2005) evaluated the effectiveness of MI provided by General Practitioners (GPs) as part of an intensive treatment programme for individuals (40-69 years) with newly diagnosed Type 2 diabetes. Measures included self-report questionnaires of perceptions of the doctor-patient relationship (Health Care Climates Questionnaire), self-determined behaviour (Treatment Self-Regulation Questionnaire), perceptions of diabetes (Diabetes Illness Perception Questionnaire, which includes the PMDQ), and diabetes self-management behaviour (DSCAQ), as well as metabolic measures (i.e., HbA1c, lipids, blood pressure) and BMI. The results suggest that, at one year follow-up, the intervention group were more motivated, reported receiving more advice from their GP, and had increased beliefs about the effectiveness of diabetes treatment. There, however, was no significant changes in behaviour (smoking, alcohol consumption, and physical activity) or physical risk factors (i.e., HbA1c, lipids, blood pressure and BMI). It is also unclear if the observed changes were due to the intensive intervention or the MI component.

In summary, the effectiveness of MI applied to diabetes is unknown, with mixed results achieved across studies evaluating MI with diabetes. Furthermore, these previous studies have varied in the measures used to evaluate outcome. Most, but not all (i.e., Knight et al., 2003), studies have included metabolic measures (e.g., HbA1c, lipids), which are the primary measures of importance in terms of diabetes outcome. As well as metabolic measures, most studies (Smith et al., 1997; Clark et al, 2003; Rubak, 2005, Brug et al., 2007) have used direct or indirect (i.e., questionnaires) measures of self-management behaviour, such as SMOBG, physical activity, or diet, providing an indication of the process by which any change in

metabolic data may have occurred. Less than half of the studies (i.e., Knight et al., 2003, Rubak, 2005; Channon et al., 2007), however, have included psychosocial measures related to diabetes, such beliefs about the effectiveness of treatment or the seriousness of diabetes. Such measures are important to include in any evaluation of treatment for diabetes, as an individuals knowledge and beliefs about diabetes and its treatment may affect metabolic control (Bradley, 1994; Gonder et al., 2002). If an individual with diabetes is 'unhappy with their treatment or seriously inconvenienced they are unlikely to be conscientious in following the prescribed treatment regimen, especially if the perceived benefits do not outweigh the psychological costs' (Bradley, 1994, p.12).

Of the studies that measured metabolic control, half (i.e., Smith et al., 1997; Viner et al., 2003; Channon et al., 2007) found improvements in HbA1c following MI, whereas no such change was found in the other half of the studies (i.e., Clark et al., 2004; Rubak, 2005; Brug et al., 2007). Similarly, of the studies that included behaviour change as an outcome measure, half (i.e., Smith et al., 1997; Clark et al., 2004) found improvements in diabetes self-management behaviour after MI, whereas no such change was found in the other half of the studies (i.e., Rubak et al., 2005; Brug et al., 2007). The only consistent finding across the previous MI studies, and this was in only two studies (Knight et al., 2003; Channon et al., 2007), was a decrease in the participants beliefs about their diabetes following MI, particularly their beliefs and concerns about the influence of diabetes on life expectancy, quality of life, and daily functioning. Additionally, all but two (i.e., Rubak, 2005; Brug et al., 2007) of these studies used specialists (typically a psychologist) to provide the MI intervention rather than usual clinical staff, such as dietitians or nurse educators, who work with the most

with individuals with diabetes, and the research was not conducted in real world conditions, with patients could be considered less motivated, who had been identified as experiencing difficulties with diabetes self-management.

Empirical studies of MI training. While studies have demonstrated that MI is effective in reducing problem behaviours, including health-related behaviours, evidence is only recently emerging regarding the effectiveness of MI training in altering practitioner behaviour consistent with MI theory. Some earlier studies (Bien, Miller & Burroughs, 1993; Carroll, Kadden, Donovan, Zweben & Rounsaville, 1994) evaluated the outcome of training in MI, including using treatment adherence ratings collected as part of assessment of treatment integrity (Rubel, Sobell & Miller, 2000). The results of these studies suggest a change in therapist behaviour post-training consistent with MI. These studies, however, tended to use only global ratings of MI consistent and MI non-consistent therapist behaviour, and did not measure client behaviour.

The Motivational Interviewing Skills Code (MISC) is a measure of proficiency in using MI, but also includes measures of client behaviour that are predictive of client behaviour change (Amrhein et al., 2003, Miller et al., 1993). There are, however, only three published studies which have utilised the MISC to evaluate training in MI.

The first such study evaluated the effectiveness of a 2-day training in MI for 22 probation counselors (Miller & Mount, 2001). They reported summary measures from the MISC, with significant increases on global ratings of proficiency in MI post-

training that were maintained at 3-month follow-up, with the total number of MI consistent responses increasing 47% from pre-training to follow-up, and a 76% increase in the ratio of reflections to questions.

Miller et al (2004) used the MISC in a RCT to evaluate methods (workshop only, workshop plus feedback, workshop plus coaching, workshop plus feedback and coaching, self-training control). Analysis of audiotape practice samples at baseline, post-training, and 4, 8, and 12 month follow-up using the MISC found that the four trained groups showed increased proficiency in MI (although the workshop only group showed only marginal gains), whereas the self-training control group did not, and that these gains were generally maintained throughout follow-up. The training groups showed significant increase in the global spirit rating; reflection to question ratio; percent complex reflections; MI consistent response ratio; and therapist talk time. They also found that the three groups that received feedback and/or coaching in addition to the workshop met the standard (i.e., global spirit and % MI consistent responses) for proficient MI at 4- and 8-month follow-up, whereas the self-training control and workshop only groups did not achieve this standard. Furthermore, they found that client (actors) responses changed in the expected direction post-training, with less resistance and more change talk. Actual client responses at 4-months follow-up, however, showed this pattern only for the workshop plus feedback and coaching group only, suggesting an advantage in the combined training methods.

In the only clinically-based study of MI training Brug et al (2007), evaluated MI training (2 days training, plus 1 day follow-up workshop and 'on demand' feedback and advice on MI-related issues) of dietitians working with patients newly

diagnosed with diabetes. In this study 38 specialist diabetes care dietitians were randomised to MI training (n=18) or no training (n=19). The outcome measures included dietitian counselling behaviour (MISC version 2.0) in the first 15 minutes of intervention sessions using transcripts of audio-tapes of sessions one month and 5-6 months post-training, and patient outcome measures (i.e., self-report questionnaires on diet, body mass index, waist circumference, and HbA1c) pre- and post-intervention. The results indicated that the dietitians who received MI training were significantly more empathic, used more reflections, and talked less than the control dietitians. While patients in both groups showed significant improvements in diet, HbA1c, BMI and waist circumference, multiple regression analysis indicated that patients who received MI had lower saturated fat intake post-intervention than controls, but no effects for HbA1c, body mass index, or waist circumference were found. The authors concluded that standard dietary counselling and MI for patients with newly diagnosed diabetes seem similarly effective, but recommended that future research evaluate the effectiveness of MI when MI is likely to be more relevant, that is, after patients with diabetes have had more experience with the difficulties of maintaining the necessary behaviour changes.

Ethical considerations in the practice of MI

Despite the positive outcomes that have resulted from MI, such as reduced alcohol and drug use, and improved health, MI has been criticised as being "manipulative" and ethically questionable. The reason for this criticism is that it involves intervening when a person is undecided about change (Miller, 1994). Miller (1994) acknowledges that because MI can be applied to persons without their request,

consent or knowledge, and because it is effective, then it is, in that sense, manipulative, but defends MI as ethically appropriate because outcomes from MI, thus far, “would be judged by many to be benevolent” (p.118).

Withers (1995) generally concurs with Miller’s (1994) defense of MI, but suggests that because MI “is proving to be such a powerful technique” it should therefore be the subject of intense investigation. In particular, it is recommended that any adverse effects of MI should be investigated, and whether there are circumstances in which it may be inappropriate, with consideration given to the motives or value judgements of the person intervening (the therapist) in determining its ethical appropriateness.

This latter point seems crucial. MI is more likely to be questioned on ethical grounds if the therapist is not adhering to the spirit of MI and is engaging in MI with the aim of making the client change. If the aim, however, is to help the client explore his or her ambivalence about change, and this involves respectfully reminding the client that they are responsible for choosing whether and how to change, then MI seems ethically defensible.

There may also be a problem with informed consent, as acknowledged by Miller (1994). Typically MI starts with the therapist inviting the client to talk about a particular behaviour (e.g., drinking alcohol) or concern, but without the explanation that the therapist's aim in discussing the behaviour is to explore the client’s motivation to change the behaviour, and in such a way that may increase the client's motivation to change. The client is therefore consenting to discuss a particular issue, but without

the full knowledge of the potential outcome. This problem may be able to be overcome in settings where the client is coming seeking assistance for a particular problem. MI could then be explained as a way of working with people that helps people change their behaviour.

In settings in which the client has been compelled or coerced to attend (e.g., in correctional settings), however, such an explanation is likely to be counterproductive and produce resistance. Even in these situations, however, it could be possible to inform the client that the intention is to discuss their thoughts and feelings about their behaviour, to gain a better joint understanding of the behaviour, not with the intention of making the individual change their behaviour, but so that they can make the best decisions for themselves regarding the behaviour. It could also be mentioned that, as a result of such discussions, some people decide that they want to change their behaviour, and others do not, but that this is the client's personal choice.

It is clear that ethical concerns about MI are likely to be reduced if the therapist emphasises that the client is responsible for choices about their own life, and is informed about the limits of confidentiality. In so doing, the client is empowered to decide on how much to disclose, as well as whether, and how, behaviour change will occur.

There will be situations where MI may not be ethically appropriate (such as with clients with active psychosis who lack insight, or perhaps with individuals with very low intellectual functioning) because the client does not have the capacity to clearly explore the pros and cons of their behaviour. Additionally, there may be

conflict in applying MI in settings where the medical model predominates, particularly if the doctor-patient relationship is a patient-provider relationship (rather than patient-centred), where the emphasis is on diagnosis (labelling), and persuading the client (trying to convince the client why they should change) and providing advice (making suggestions about how they could go about it) about changing problematic behaviour, all of which are contraindicated in MI.

Future Research

MI appears to hold considerable promise. Not only does it appear to be effective (i.e., clients change behaviour that they have been engaging in for some time), but it appears to work in relatively small doses (e.g., 1-4 sessions) with relatively large effects (i.e., MI produces similar effects to much longer treatments). Furthermore, it appears to be most effective with clients who appear less ready, or less motivated, for change, or who are more angry and negative, attributes which are often considered markers of poor prognosis.

While MI seems to work by reducing client resistance (Miller et al., 1993), it remains unclear as to how it has its effect and what elements of MI are essential (Miller, 1996). Further research needs to establish the process of MI and its key components. For example, little is known on what is the best way to structure sessions, or which are the optimal methods for responding to resistance.

It is also unclear which individuals would benefit most from MI and which specific motivational intervention (i.e., DCU, MET, Brief MI) would be of most benefit for a particular individual. In addition, researchers need to give a clear description of the MI intervention they are evaluating, including any modifications they have made to fit with the particular target problem or client population.

Further research is also needed into whether there are any advantages of integrating MI with CBT or BT. MI could be viewed as the first stage of intervention, particularly with clients in the precontemplation or contemplation stages of change. This could then be followed with CBT or BT when clients are further along the stages of change (i.e., in preparation, action or maintenance) and are likely to gain most benefit from a more action-oriented approach, focusing on building skills or strategies for behaviour change.

There are few controlled studies evaluating the effectiveness of MI with new problem areas such as eating disorders, criminal behaviour, or health problems (such as diabetes), although MI has been identified as being potentially useful in these areas. Continued outcome research into MI applied to new problem areas, such as health behaviour change, is required. This research should include a description and evaluation of the MI training provided to the interventionists, as well as measures of treatment integrity.

The Present Research

The present research is an evaluation of the effectiveness of MI applied to diabetes. The aim was to evaluate the effect of MI on both metabolic and behaviour change measures, as well as psychosocial aspects related to diabetes, when the MI intervention was provided by usual clinical staff (i.e., nurse educators and dietitians) in real world conditions, with patients could be considered less motivated, who had been identified as experiencing difficulties with diabetes self-management.

The MI intervention specifically evaluated in the present research was MET. MET was chosen as the form of MI to be evaluated because it is a brief, time-limited form of MI, and therefore would provide consistency across individuals and studies, and would provide participants with time-limited ongoing contact which was considered important for behaviour change (Kelleher, 1988; Mazzuca, 1983; Marteau & Kinmonth, 1988).

A broad range of outcome measures were used. Because of its central place in the health of individuals with diabetes, measures of metabolic control were used as the primary outcome measures. Given that hyperlipidaemia tends to be an important focus of diabetes treatment, metabolic data included lipids as well as blood glucose. Diabetes self-management behaviours (e.g., diet, exercise, glucose testing) were also included as dependent measures to assess the process of change. Also, a range of psychosocial measures (i.e., knowledge, beliefs, emotional adjustment, treatment satisfaction) were included in attempt to assess the broader impact of the intervention. Furthermore, consistent with the recommendations of Miller and Rollnick (2002), the

research included measures of treatment integrity and a qualitative analysis of the process of change itself.

In order to increase the generalisability of the results, the research was conducted in a clinical setting, with health practitioners at the setting trained to provide MI. Exclusion criteria were also kept to a minimum and participants included patients with both Type 1 and Type 2 diabetes. This, however, also placed constraints on the research design that could be used. Specifically, in order to be as least disruptive as possible to the usual clinic practice, the number of staff who could be involved in the research (as interventionists or to assist data collection) was small, and there was the expectation that the research would fit in with normal clinic protocols (such as existing data collection) as much as possible.

Hence, single-case research design was used (Barlow, Hayes & Nelson, 1984; Blampied, 1999, 2000; Hersen & Barlow, 1976), as this required that only a small number of staff and patients be involved and, therefore, was more suited to a busy clinical setting. Single-case research design was also considered appropriate because the intervention being evaluated was relatively innovative. This enabled the evaluation of MI applied to diabetes management without the need for large numbers of individuals being exposed to a relatively novel intervention. A non-concurrent multiple-baseline design across participants (Watson & Workman, 1981), in which the intervention is applied in sequence across participants, was used as this was particularly suited to a clinical setting where referrals arrive over time and there are not necessarily large numbers of potential participants available or needing assistance at any one time.

Single-case methodology also had the advantage of preserving the complexity of the real-life situation. For example, while treatment of diabetes has the overall goal of reducing blood glucose and cardio-vascular risk factors, the steps to achieving this may involve a number of different self-management behaviours (e.g., diet, exercise, medication use, glucose monitoring), which may vary from individual to individual, as well as within an individual, across time. This also enabled patients to commence intervention without assumptions having been made that a particular behaviour would be the target for change, which is consistent with the spirit of MI. Additionally, as well as only requiring a small number of staff to be involved as interventionists in the research, the use of a single-case design also enabled an evaluation of the effect of MI training, and comparison with standard practice (PE), without the risk of what was learnt from MI training contaminating their standard practice.

The present research is also an example of the scientist-practitioner model of clinical psychology in practice. The 1949 Boulder Conference (Raimy, 1950) defined a clinical psychologist as a scientist-practitioner who was a consumer of new research findings and an evaluator of clinical interventions, but also as a researcher who produced data from his or her own clinical practice to inform the scientific community (Barlow et al., 1984). The intent of the model was to encourage the integration of research into clinical practice, with practicing clinical psychologists contributing to the evolution of psychological knowledge as well as providing psychological services (Haynes, Lemsy & Sexton-Radek, 1987). The scientist-practitioner model, however, seems to be infrequently adopted by clinicians (Haynes et al., 1987).

It was also hoped that the design of the research would be such that practitioners would view the research as being applicable to their clinical situation, and, therefore, go some way towards ‘bridging the gap between research and clinical practice’ (Anthony, 2005, p. 162; Barlow et al., 1984). Glasgow et al (2006) point out that the questions and concerns of health practitioners are often related to external validity. In particular, practitioners are concerned about whether research findings apply to their setting and practice, and their efficiency and cost-effectiveness when delivered in everyday clinical settings (Anthony, 2005; Glasgow et al., 2006).

There is generally a slow diffusion of innovations and the slow movement of evidence-based clinical interventions into clinical practice (Anthony, 2005; Balas & Boren, 2000; Glasgow et al., 2006; Kerner, Rimmer & Emmons, 2005; Leeman, Jackson & Sandelowski, 2006; Rogers, 2003). Furthermore, Leeman et al (2006) point out that ‘diabetes self-management exemplifies the limitations encountered in efforts to translate research findings into practice’ (p.171). They point out that despite the DCCT and UKPDS having ‘shown that improving glycaemic control can prevent or delay diabetes-related complications’ (p.171) and the growing body of research on diabetes self-management interventions, ‘many patients are not receiving support for their self-management’ (Glasgow & Strycker, 2000), and approximately 54% of people in the United States with Type 2 diabetes have glycaemic levels greater than current target levels for control (Clark et al., 2000)’ (p.171).

Consequently, the present research incorporated characteristics of Practice-based Clinical Trials (PCTs; Tunis, Stryer & Clancy, 2003) and Practical Behavioural Trials (PBTs; Glasgow et al., 2006), which have been suggested as strategies for research investigating interventions in clinical practice settings, which may facilitate dissemination (Glasgow et al., 2006; Kerner et al., 2005; Tunis et al., 2003). Tunis et al (2003) suggest that PCTs should answer questions of key stakeholders (e.g. clinicians, decision makers), and assess multiple and relevant outcomes, including generalisation, quality of life, and cost. They also suggest that PCTs should compare clinically viable alternative interventions, as “too often, a new generation of trials supporting a new treatment fails to perform comparisons against (these) already-established treatments (Glasgow et al, 2006). Tunis et al (2003) further suggest that PCTs should recruit a diverse, heterogeneous sample and evaluate robustness across key subgroups, and include multiple, representative interventionists and settings. Broadening inclusion criteria enables studies to include participants who are more representative (e.g., higher risk and multimorbid patients) of those seen in clinical practice, while the inclusion of more representative interventionists and settings assist with addressing questions regarding whether the resources, workloads and time dedicated to a given trial versus other duties is comparable enough to allow generalisation to real life clinical settings (Glasgow et al., 2006).

Glasgow et al (2006) applied the characteristics of PCTs to what they call “practical behavioural trials” (PBTs, p.6) in which either the intervention employs behavioural strategies, procedures or theory; or the primary outcome involves behaviour change on the part of patients, clinicians, families or larger groups (e.g., changes in work place policies and practice). Glasgow et al (2006), however, suggest

that PBTs should also specify the level of training/expertise necessary and the amount of training provided and include measures of behaviour change at multiple levels (e.g., patient, clinician, system), including implementation of the intervention by representative clinical staff.

In addition, participatory action research (PAR) methodology (Boog, Keune & Tromp, 2003) was also utilised, as recommended by Glasgow et al (2006). Carr and Kemmis (1986) describe PAR as “a form of self-reflective enquiry undertaken by participants in social situations to improve the rationality and justice of their own practices, and the situations in which the practices are carried out” (p.162). Thus, PAR can be understood as a cycle of reflection, planning, action, and observation (McTaggart, 1997).

PAR is typically used in real situations, with a primary focus on solving real problems (O’Brien, 2001). Therefore, those who apply PAR methods are often practitioners who wish to improve understanding of their practice, with a cornerstone of action research being that knowledge is derived from practice, and practice informed by knowledge, in an ongoing process (O’Brien, 2001). Thus, PAR also rejects the notion of researcher neutrality, with the “understanding that the most active researcher is often one who has most at stake in resolving a problematic situation (O’Brien, 7).

In PAR “you get the people affected by a problem together, figure out what is going on as a group, and then do something about it” (Kidd & Kral, 2005, p.187). Often, then, the first task in action research is for the researcher to organise a forum in

which dialogue is initiated and experiences shared, so that what action research adds is “the inclusion of some of the people being studied in the identification of the problem and research question” (Kidd & Kral, 2005, p.190).

The author was employed as a Clinical Psychologist at the Diabetes Centre, Canterbury District Health Board (New Zealand) when the idea of the research developed. She was frequently referred patients who were described as “unmotivated” or struggling with motivation for diabetes self-management from other health professionals working at the Centre, and used MI to work successfully with these patients. Training other health practitioners, who typically had first contact with the patients, in MI developed as a notion that had the potential to benefit all concerned. The patients would be exposed to a way of working that was likely to facilitate their motivation for change and therefore reduce their exposure to what potentially could be perceived as a failure experience, the other health professionals would feel empowered with another tool for working with people who seemed to be struggling with behaviour change, and the Clinical Psychologists would be able to focus on assisting patients who had more severe, clinical disorders (e.g., depression, anxiety, eating disorders) affecting their diabetes management.

In order to assess whether MI would be an attractive option to the other health professionals working at the Centre, and following PAR methods, a teaching session which introduced MI was held, after which their thoughts about MI and its potential application to their work were sought. Overall, there was considerable enthusiasm for MI and its potential use in diabetes. In particular, the notion of stages of changes and attempting to assess where a patient was with regards to this was considered helpful.

The MI skills that were considered to be of potential benefit for clinical practice were listening to patients more, and eliciting ideas/solutions from patients, rather than trying to solve the patients' problems.

A number of potential barriers to using MI at the Centre were identified however. These included work place issues, such as time pressure and lack of flexibility with appointments, but also training needs in terms of specific training and ongoing supervision for skills development, as well as questions regarding the effectiveness of MI and its acceptability to patients.

Consequently, the research programme was developed to answer these questions, and those identified in previous MI research, as well as to address areas of weakness identified in previous research. Specifically health practitioners would be trained, and receive ongoing supervision, to provide MI, which would be provided within a clinical setting to patients experiencing difficulties with diabetes self-management, and MI would be compared to an active treatment (i.e., PE) using outcome measures which include diabetes outcome and self-management behaviour, as well treatment integrity.

The main aims of the research, therefore, were to evaluate: (1) if MI was effective when applied by health practitioners in a real-life clinical setting with patients experiencing difficulties with diabetes self-management; (2) how MI compared to the then current standard treatment – PE (Studies 1-2); and (3) the effects of MI training on practitioner and patient behaviour (Study 3). Specific hypotheses (Studies 1-2) were that MI would lead to improved diabetes outcome (lowered blood

glucose and improved lipids) through improved diabetes self-management (e.g. self-monitoring of blood glucose, dietary compliance, exercise), and would be more effective than PE. Hypotheses for Study 3 were that training in MI, plus supervised practice, would lead to the practitioners behaving in ways consistent with MI and as a result the participants would exhibit less resistance and increased change talk than participants receiving PE.

STUDY 1: TREATMENT EVALUATION

The aim of this study was to evaluate the effectiveness of MET when applied by DNEs in a real-life clinical setting with patients experiencing difficulties with diabetes self-management, and to compare the effectiveness of MET to that of PE. Specific hypotheses were that MET would lead to improved diabetes outcome (i.e., lower HbA1c and improved lipid profile; Hypothesis 1) through improved diabetes self-management (viz self-monitoring of blood glucose, diet, exercise; Hypothesis 2), and would be more effective than PE (Hypothesis 3). Additional hypotheses were that MET would be considered an acceptable intervention to participants (Hypothesis 4), and there would not be any adverse effects from MET on the participants' adjustment to diabetes or beliefs about the seriousness of diabetes or the effectiveness of its treatment (Hypothesis 5). It was also hypothesised that there would be an increase in motivation to change in MET participants (Hypothesis 6), whereas PE participants would show an increase in knowledge about diabetes (Hypothesis 7).

Method

Procedure

Participants

Patients (aged 16-69 years) who had been referred to DNEs at a Diabetes Centre (an outpatient service accepting referrals from primary medical practitioners (i.e., GPs throughout a major metropolitan area and adjacent rural areas) for further assistance with managing their diabetes (Type 1 or Type 2), and who had been diagnosed with diabetes for at least 12 months, were approached regarding participation in the study. Participants were not randomly assigned to intervention. All participants continued to receive TAU from their GP throughout the study.

Initially, 16 consecutive referrals to the DNEs were approached regarding participation in the PE phase. Of these, five declined to participate. Another two agreed to participate but subsequently withdrew - one because it was considered best for her health care that she received an alternative intervention, and the other because he did not wish to change to the blood glucose meter being used for the research. Thus, there were nine participants in the PE phase.

Once the intervention in the PE phase had been completed and the DNEs had received training in MET, 16 consecutive referrals to the DNEs were approached regarding participation in the MET phase. Of these, four declined to participate. Another three agreed to participate but subsequently withdrew - one because of work

commitments and two because they no longer wished to receive intervention from the centre. Thus, there also were nine participants in the MET phase.

Patients who agreed to participate in the study and who completed PE tended to be female Caucasians with Type 2 diabetes, with more males declining to participate in the study. The age range for those who completed PE was 31-64 years, with a similar mean age to those who declined participation (Table 1).

Table 1. Characteristics of participants – PE and MET

		Declined	Withdrew	Completed
Diabetes	PE			
	Type 1	2	0	1
	Type 2	3	2	8
Gender	Male	5	1	3
	Female	0	1	6
Ethnicity	Maori		0	1
	Caucasian		2	8
Age (years)	Mean	48.6	56.0	48.9
	Range	32–58	54–58	31–64
Diabetes	MET			
	Type 1	0	2	4
	Type 2	4	1	5
Gender	Male	2	1	5
	Female	2	2	4
Ethnicity	Maori		1	2
	Caucasian		2	7
Age (years)	Mean	53.0	42.3	44.0
	Range	45–65	21–56	21–69

Participants, mostly Caucasians, with Type 1 or Type 2 diabetes, of either gender, completed MET, but more patients with Type 2 diabetes declined participation. The mean age for those completing MET was nine years lower than those who declined participation, but similar to those who withdrew from the study (Table 1). There was a statistically significant difference between the PE and MET participants in terms of age, with the MET participants (95% CI=34-54 years of age) being younger than the PE participants (95% CI=43-55 years).

The MET participants, however, tended to have been diagnosed with diabetes for longer (95% CI=10-15 years since diagnosis) than the PE participants (95% CI=3-11 years), perhaps because there were more participants with Type 1 diabetes (which tends to be diagnosed at an earlier age) in the MET phase (Table 2). While the duration of diagnosis was not statistically equivalent between the two groups, it was also not significantly different at the .05 level, resulting in statistical indeterminacy.

Table 2. Duration (years) since diagnosis of diabetes

Participants	95% CI	Different (.05 level)	Equivalent ($\Delta=6.33$)
PE	3.2339–11.2105	ns	ns
MET	10.4325–15.1231	ns	ns

* $\Delta=1$ standard deviation of PE and MET samples

ns=not statistically significant at .05 level

For more detailed description (i.e., reason for referral, diabetes complications, other health problems, medication and employment status) of PE and MET participants, and individual case descriptions see Appendix 1.

Staff

Three DNEs agreed to participate in the study, but one subsequently withdrew (having obtained alternative employment) at the end of the PE phase. All of the nurses had considerable experience working with diabetes, with the two nurses who remained in the study both having worked in diabetes for nine years, and registered as nurses for 23 and 25 years respectively.

Intervention

PE. The standard intervention provided at the Diabetes Centre at the time that this research began, comprised the provision of information and advice about diabetes and diabetes self-management. This was provided within a patient participation and collaboration context, which also included behavioural counselling techniques, such as setting small achievable goals. The duration, number and frequency of sessions were determined, according to usual clinic practice, by the DNE in consultation with each participant however, PE typically comprised 20 minute sessions on a monthly basis.

MET. Comprised four 30-40 minute sessions of MI plus personalised feedback conducted over six weeks (on weeks 1, 2, 4 and 6). While it was not always possible maintain this schedule of appointments (due to illness, holidays, etc), appointments were re-scheduled as close to this as possible.

Training

The DNEs received two days (12 hours) training in MET provided by two trainers experienced in training MI, one of whom was the author. The training consisted of didactic teaching, modelling by the trainers and video-taped demonstrations, and role-playing with feedback, using adult education principles (Kolb, 1984; Reece & Walker, 1997). Additionally, the DNEs were provided with a manual (Appendix 2) adapted from Sellman, Sullivan and Dore's (1996) manual, which outlined key MI principles, strategies and techniques, and the process for MET.

Design

Two quasi-experimental designs were used, involving both between- and within-participant comparisons (Wood, 1981). A non-equivalent, control group design (Wood, 1981), with pre- and post-intervention measures, was used to evaluate any difference in effectiveness between MET and PE (i.e., control). Additionally, a non-concurrent multiple baseline design (Watson & Workman, 1981) across individuals (n=9 per intervention) was used. This involved the intervention (PE or MET) being applied in sequence to individual participants, while baseline data was collected for succeeding individuals.

Usually in a multiple baseline design baseline commences with all individuals at once and continues until the behaviour for each person is stable, at which time the intervention is applied to only one of them while baseline conditions are continued for the others (Kazdin, 1982). This, however, was not possible due to referrals arriving at

the Diabetes Centre over time (i.e., rather than a number of individuals all being referred at the same time) and because, for ethical reasons, it was considered inappropriate to leave individuals identified with difficulties with diabetes self-management in extended baseline periods, while waiting for the intervention to be applied to preceding participants or for baseline data to become stable.

Nevertheless, this provided an opportunity to test if the results obtained could be replicated across individuals. Replication of an intervention to establish its efficacy is considered critical with single-case designs (Sidman, 1960; Chambless & Hollon, 1998), with the number of baselines contributing to the strength of the demonstration (Kazdin, 1982). Because of the possibility of inconsistent effects of the intervention across individuals Kazdin (1982) suggests the inclusion of several baselines beyond a minimum of two or three to clarify the effects of an intervention.

A further variation to a single case design also became possible (Part B) after completion of the main PE and MET phases, when the participants who received PE were offered (at least 15 months after the completion of PE) the opportunity to receive MET, and this was accepted by three participants (Cases 4, 7, and 9) – each of whom had been unsuccessfully treated by PE in Part A. This provided a unique design opportunity, allowing the effectiveness of PE and MET to be evaluated within the same individual, provided by the same DNE, thereby allowing more direct comparison of the two interventions by reducing variables (i.e., therapist effects or individual differences) which may have impacted on outcome, with the advantage of a lag period between interventions during which any previous effect of treatment could be expected to “washout”.

Measures

Table 3 provides a summary of the outcome measures. Diabetes outcome (i.e., HbA1c and lipid profile) was the primary outcome measure, with the expectation that HbA1c would decrease post-intervention and that the participants' lipid profiles would show improvements consistent with improved metabolic control. There were also a number of intermediate process variables, which included measures of diabetes self-management behaviour (i.e., self-monitoring of blood glucose - SMOBG, diet, exercise, use of medication), weight, and psychosocial measures assessing beliefs about and adjustment to diabetes, diabetes knowledge, readiness to change, and treatment satisfaction. Additionally, measures of treatment integrity and cost were included.

Table 3. Summary of outcome measures

Measure	Baseline	Intervention	2 week post	3 month follow-up	6 month follow-up	12 month follow-up
Primary outcome						
HbA1C	✓		✓	✓	✓	✓
Lipids	✓		✓	✓	✓	✓
Intermediate process variables						
SMOBG	✓	✓	✓	✓	✓	✓
Diet	✓	✓	✓	✓	✓	✓
Exercise	✓	✓	✓	✓	✓	✓
Medication	✓	✓	✓	✓	✓	✓
PMDI	✓		✓			✓
PAID	✓		✓			✓
DKT	✓		✓			✓
SOCRATES	✓		✓			✓
GCC		✓				
TEI			✓			

HbA1c=Glycated Haemoglobin

SMOBG=Self-monitoring of Blood Glucose

PMDI=Personal Models of Diabetes Interview

PAID=Problem Areas in Diabetes

DKT=Diabetes Knowledge Test

SOCRATES=Stages of Change Readiness and Treatment Eagerness Scale

GCC=Goals for Change Checklist

TEI=Treatment Evaluation Inventory

Primary outcome

Baseline, post-intervention and 3-, 6- and 12-month follow-up data were collected on diabetes outcome using fasting glycated haemoglobin (HbA1c), which measures the average blood glucose over the previous 8-10 weeks (Krishnamurti & Steffes, 2001); and fasting lipid tests, including total cholesterol, high density

lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL), triglycerides, and risk ratio (total cholesterol divided by HDL) which provides an estimate of risk of coronary heart disease.

HbA1c and lipid results were graphed for each participant, with the following targets:

HbA1c - less than 7%, which represents tight diabetes control (New Zealand Guidelines Group, 2003).

Total cholesterol - less than 5.5 mmol/L. Levels greater than this are associated with a significantly increased risk of coronary artery disease in all age groups (Linton & Fazio, 2003).

Triglycerides - less than 1.7 mmol/L. Levels greater than this are generally accepted as an independent risk factor for coronary artery disease (Linton & Fazio, 2003).

LDL cholesterol - less than 2.5 mmol/L. LDL cholesterol is often calculated rather than measured directly although this method is unreliable if levels of triglyceride are 4.5 mmol/L or greater (Linton & Fazio, 2003).

HDL cholesterol - greater than 1.0 mmol/L. Low levels of HDL cholesterol and high levels of LDL cholesterol are associated with an increased risk of atherosclerotic vascular disease (Linton & Fazio, 2003).

Risk ratio - less than 5.0 mmol/L. This is calculated by dividing the total cholesterol by the HDL cholesterol, with ratios greater the 5.0 mmol/L associated with increased risk of coronary artery disease.

A 0.5% change in HbA1c, which represents one standard deviation (Butler et al, 1995), was considered clinically significant. This level of reduction in HbA1c has been found to be associated with a 25% reduction in the risk of retinopathy (DCCT Research Group, 1996). Due to the complexity in analysing the clinical significance of the lipid data, a diabetes physician (who was blind to condition) provided a clinical interpretation of the lipid data in terms of whether each participant's lipid profile showed an overall improvement or deterioration, or was essentially unchanged.

Additionally, HbA1c and lipid results were analysed using inferential confidence intervals (Tryon, 2001) to evaluate statistical difference and equivalence within (i.e., PE participants and MET participants) and between groups (i.e., PE compared to MET) over time. This involved establishing a descriptive 95% confidence interval (CI) about each of two means and then concluding that there is:

1. statistical difference ($p < .05$ level) if the inferential CIs do not overlap
2. statistical equivalence if the range (i.e., the lower CI limit of the lesser mean to the upper CI limit of the greater mean) fit within the delta (Δ) bound of indifference (i.e. the maximum difference that is unimportant or can be dismissed on substantive grounds). The coefficients of variation (CV) for HbA1c and lipids were used to calculate delta, thereby accounting for biological variation (Fraser, 2001). The CVs were as follows: HbA1c=5.6%; total cholesterol=15.2%; triglycerides=37.2%; HDL cholesterol=19.7%; and LDL cholesterol=25.7%.
3. statistical indeterminacy in all other cases.

Appendix 3 illustrates how statistical difference and equivalence was evaluated for independent and dependent means. Unless otherwise stated, results reported as statistically different are those that were found to be both statistically different, and not statistically equivalent, at the .05 level. Similarly, results reported as statistically equivalent were ones that were found to be statistically equivalent and not statistically different at the .05 level.

Additionally, the effect size for results that were found to be statistically different were calculated using Cohen's d (Cohen, 1992) representing the difference between pre- and post-intervention results divided by the standard deviation of the mean score at baseline. The magnitude of the effect was interpreted using Cohen's (1997) guidelines, with $d=.2$ representing a small effect, $d=.5$ a moderate effect, and $d=.8$ a large effect.

Furthermore, at the commencement of the study participants were given a blood glucose meter (Precision QID) on which they could self-monitor their blood glucose. The meter contained a memory which allowed data to be down-loaded at a later date to give a full history of blood glucose levels. Data from SMOBG were graphed for all participants, with the target level set on the meter at 3.5-7.8 mmol/L. Due to the considerable variability in self-monitored blood glucose levels, the data were smoothed (using Sigmaplot's running average algorithm, taking a running average of three data values in a series) to enable easier detection of trends. The mean and standard deviation for each phase was also calculated to assist visual analysis.

Intermediate process variables

Diabetes self-management behaviour. At the end of each PE and MET session participants and the DNEs were asked to independently state the goals for change using the Goals for Change Checklist (GCC). The GCC (Appendix 4) was developed for the study based on common goals for diabetes self-management. If the participant and DNE both selected a diabetes self-management behaviour (e.g., increased SMOBG) as a goal for change, then these data were included for analysis.

Because at the commencement of the study, it was unknown what diabetes self-management behaviour(s) would be selected by the participants as a target for change, all participants were asked to record on a daily basis their diet (i.e., food type, amount, cooking method), exercise, and medication use for at least one week at baseline, throughout intervention (PE or MET), for two weeks post-intervention, and for one week at 3-, 6- and 12-month follow-up. The request to record this information was also consistent with the then current practice at the Diabetes Centre. Dietary compliance was assessed as the percentage of meals/snacks per day which complied with the recommended diabetic diet (i.e., low fat, low sugar, high fibre). Exercise was measured as the number of episodes (irrespective of duration) of physical activity (e.g., gardening, walking) per day.

The participants were also weighed (also consistent with the then current practice) at baseline, post-intervention and 3-, 6- and 12-month follow-up. Weight was graphed if it was a goal for change for the participant.

The memory in the blood glucose meter which the participants were given to self-monitor their blood glucose allowed data to be down-loaded to give a full history of the frequency of SMOBG. At baseline, participants were not given any specific instructions regarding the frequency in which SMOBG should occur, but were simply instructed to engage in SMOBG as per previous medical advice. Data on the frequency of SMOBG from the meters were graphed for all participants.

Psychosocial measures. The following measures were administered at baseline, two weeks post-intervention, and at 12-month follow-up:

Personal Models of Diabetes Interview (PMDI, Glasgow, Hampson, Strycker & Ruggiero, 1997) - a comprehensive semi-structured interview designed to assess patients' representations of their diabetes, including beliefs about symptoms, disease course, consequences, cause, and treatment effectiveness. Three composite scores (which is the mean of the component items, which were rated on a 5-point Likert scale, from 1=not at all to 5=extremely) can be calculated based on the individuals responses: cause (i.e., internal or external factors); treatment effectiveness (i.e., beliefs about following standard treatment regimens and these regimens on the control of diabetes); and seriousness (i.e., beliefs and concerns about the influence of diabetes on life expectancy, quality of life, and daily functioning).

Research suggests that personal models for chronic diseases guide an individual's processing of information and subsequent health behaviour such as the patient-provider interaction and self-management (Petrie, Weinman, Sharpe & Buckley, 1996; Glasgow, Hampson, Strycker & Ruggiero, 1997; Scharloo & Kaptein, 1997). In particular, seriousness and treatment effectiveness have been found to be

important cognitive dimensions which predict diabetes self-care behaviour and outcome (Hampson, et al., 1990; Hampson et al., 1995; Skinner & Hampson, 2001). For example, Hampson et al, (1995) found that beliefs about treatment effectiveness and disease seriousness in diabetes were prospectively predictive of dietary behaviour and physical activity (i.e. higher treatment effectiveness and seriousness scores were correlated with improvements in diabetes self-management behaviour). Additionally, low treatment effectiveness, and high seriousness correlated significantly with negative affect and several aspects of quality of life.

Problem Areas in Diabetes (PAID, Polonsky et al., 1995) - a 20 item questionnaire measuring emotional adjustment to diabetes. Each item represents a unique area of diabetes-related distress, ranging from anger ('feeling angry when you think about having diabetes and living with diabetes') and interpersonal distress ('feeling that your friends and family are not supportive of your diabetes efforts') to frustration with aspects of diabetes management ('not having clear and concrete goals for your diabetes'). Patients rate degree to which each item is a problem for them on a 6-point Likert scale, from 1 (no problem) to 6 (serious problem). The score is the sum of the 20 PAID items, multiplied by 1.25, giving a final score ranging from 0-100.

High total scores on the PAID indicate greater levels of diabetes-related emotional distress. Welch, Jacobson and Polonsky (1997) recommend a cut-off score one standard deviation above the mean (i.e., $54.5 + 23.1$) as an overall measure of the emotional burden of diabetes or 'diabetes burnout'. Scores on the PAID have been found to correlate with engagement in self-management behaviour, to significantly

predict glycaemic control (i.e. lower scores predict better self-management and improved glycaemic control), and to be sensitive to change in diabetes-related distress following educational and psychosocial interventions for diabetes (Welch, et al., 1997; Welch, Weinger, Anderson & Polonsky, 2003).

Diabetes Knowledge Test (DKT) - developed by the Michigan Diabetes Research and Treatment Centre (Fitzgerald, Anderson, Funnell, Hiss, Hess, Davis & Barr, 1998) as a measure of general knowledge of diabetes, such as diet, blood glucose, consequences and insulin. It consists of 23 items with multi-choice responses, the first 14 of which are appropriate for individuals who do not use insulin. The total score is the percentage correct responses, which for individuals who use insulin is calculated over the whole 23 items, whereas for individuals who do not use insulin this is calculated for the first 14 items only.

Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) - a 40 item questionnaire developed for use with alcohol abuse (Miller & Tonigan, 1996) as a measure of stage of change based on the trans-theoretical model of change (Prochaska & DiClemente, 1982; Prochaska et al., 1992), which has been modified for use with diabetes by adapting the wording of each item (Trigwell, Grant & House, 1997). For example, item 1 was changed from ‘I really want to make changes in my drinking’ to ‘I really want to make changes in how I look after my diabetes’.

The SOCRATES uses 5-point Likert scales, ranging from 5 (strongly agree) to 1 (strongly disagree), across five subscales intended to correspond to Prochaska and Di Clemente’s (1992) pre-contemplation, contemplation, preparation (or

determination), action and maintenance stages of change (Miller & Tonigan, 1996). The five subscale scores are calculated by summing the scores for the eight items in each subscale. The motivational stage is then determined according to which subscale has the highest score. If the maximum score is shared by more than one subscale, a single stage of change cannot be allocated (Trigwell et al., 1997). When this occurred in the present research, this was noted in the individual case results, and the lowest stage of change which shared the maximum score was used for graphical analysis. Results were graphed on a scatter plot (Blampied, 2005), with baseline stage of change on the x-axis and post-intervention stage of change on the y-axis, and then with post-intervention stage of change on the x-axis and 12-month follow-up on the y-axis. This meant that if the stage of change was the same at both measurement points, then the data point would fall on a diagonal line. Any change in motivation then, would be seen in either the data point falling above (i.e. an increase in stage of change) or below (i.e. a decrease in stage of change) this diagonal line.

Treatment credibility - at the end of intervention, treatment credibility was measured by participants evaluating the intervention they received using the Treatment Evaluation Inventory – TEI (Kazdin, 1984), which was modified so that it was suitable for use with adults with diabetes (Appendix 5). The TEI uses a 7-point Likert scale, ranging from 1 (not at all acceptable) to 7 (very acceptable) across four dimensions – approval, fairness, humaneness, and effectiveness. Research has demonstrated the factorial integrity and internal consistency of the TEI (Kazdin, 1980), and that the TEI may be modified to make it more appropriate for use in a variety of clinical settings (Reimers, Wacker, Cooper & de Raad, 1992; Kelley, Heffer, Gresham & Elliott, 1989).

Questionnaire data were also analysed using inferential confidence intervals (Tryon, 2001) to evaluate statistical difference and equivalence within (i.e., PE participants and MET participants) and between groups (i.e., PE compared to MET) over time. For the current study Δ was set at one standard deviation. Additionally, the effect size (Cohen, 1992, 1997) was calculated for any statistically significant result.

Jacobson and Truax's (1991) reliable change index (RC) was used to determine whether changes that occurred in an individual participant's questionnaire data were clinically significant (see Appendix 6 for an explanation of how RC is calculated). An RC greater than 1.96 would be unlikely to occur ($p < .05$) without actual change.

Treatment integrity

To ensure treatment integrity (Kazdin, 1992) each intervention session was audio-taped. Each MET session was reviewed by the primary author, and feedback given to the DNE, to ensure that the therapeutic procedures were carried out as intended. Further, to provide a measure of treatment integrity one audiotape for each PE and MET participant (30% of sessions) was randomly selected and reviewed by an independent rater and judged as being either a PE or MET session. The independent rater was a clinical psychologist who had worked in diabetes and had training in MI, but who was blind to condition.

Cost: Resource utilisation

The number of appointments that participants attended (or missed) at the Diabetes Centre during intervention and over the course of follow-up were collated from their clinical files. This enabled the interventions to be evaluated, and compared, from a resource utilisation perspective.

Results: Part A

The Results of Part A refer to the evaluation of the effectiveness of PE and MET with the original 18 participants (i.e., n=9 PE and n=9 MET). Results from the primary outcome measures (i.e., HbA1c and lipids) will be presented first, following the results from the intermediate process variables comprising self-management behaviour and psychosocial measures. The results of statistical tests (i.e., group data) will be presented first, followed by evaluation of clinically significant change (i.e., individual data).

A range of goals were selected by both PE and MET participants (Table 4), including dietary, exercise, and SMOBG goals. More MET participants, however, selected increased SMOBG as a goal and more MET participants selected more than one diabetes self-management goal.

Table 4. Self-management goals

Goal	PE	MET
Increase SMOBG	3	7
Increase exercise	2	2
Dietary compliance	2	2
Regular eating	1	1
Weight loss	2	1

Primary outcome measures: Diabetes outcome

Blood glucose

Statistical tests of group data. PE HbA1c results were not statistically equivalent at baseline, post-intervention and during follow-up (Table 5), with results tending to be lower post-intervention and at 3-, 6- and 12-month follow-up than at baseline. The difference, however, was not statistically significant, resulting in statistical indeterminacy.

MET HbA1c results at baseline, post-intervention and follow-up were not statistically equivalent (Table 5), with results tending to be lower post-intervention and throughout follow-up, similar to PE. The HbA1c results (with the exception of 6-month follow-up), however, were also not statistically different, resulting in statistical indeterminacy. The statistically different results at 6-month follow-up suggest that the MET participants' glycaemic control improved from baseline to 6-month follow-up, with a large ($d=1.0$) effect size.

Table 5. HbA1c means, inferential confidence intervals and results of statistical tests – PE and MET

Time	Mean	r	95% CI	Different	Equivalent
PE					$\Delta^1=.47\%$
Baseline	8.867		8.09–9.65		
Post-intervention	7.917	.2525	7.52–8.31	ns	ns
Baseline	8.867		8.51–9.23		
3-month follow-up	8.329	.8153	7.98–8.87	ns	ns
Baseline	8.867		8.03–9.70		
6-month follow-up	7.583	.8880	7.09–8.08	ns	ns
Baseline	8.867		8.49–9.24		
12-month follow-up	8.843	.8700	8.24–9.45	ns	ns
MET					$\Delta^2=.55\%$
Baseline	9.767		9.43–10.11		
Post-intervention	9.575	.8761	9.17–9.74	ns	ns
Baseline	9.767		9.18–10.35		
3-month follow-up	8.856	.7705	8.59–9.21	ns	ns
Baseline	9.767		9.40–10.14		
6-month follow-up	8.513	.3437	8.30–8.61	*	ns
Baseline	9.767		9.37–10.16		
12-month follow-up	9.450	.8144	9.00–9.90	ns	ns

r=Pearson's correlation

Δ^1 =1 CV of PE baseline mean

Δ^2 =1 CV of MET baseline mean

*=statistically significant at .05 level

ns=not statistically significant at .05 level

At baseline, PE participants' HbA1c results were not statistically equivalent to the MET participants' HbA1c results (see Table 6, PE tended to be lower), although the difference was not significantly different, resulting in statistical indeterminacy. Post-intervention the PE participants' HbA1c results had declined to the extent that they were statistically different from the MET participants' results. At 3-, 6- and 12-month follow-up, however, the MET participants' HbA1c results decreased to the point where they were not statistically different to the PE participants. They, however, were also not statistically equivalent, resulting in statistical indeterminacy.

Table 6. HbA1C means, inferential confidence intervals and results of statistical tests – PE vs MET

	Mean	95% CI	Different	Equivalent ($\Delta \geq .5\%$)
<i>Baseline</i>				
PE	8.867	8.04–9.70	ns	ns
MET	9.767	8.86–10.68		
<i>Post-intervention</i>				
PE	7.917	7.48–8.35	*	ns
MET	8.856	8.67–10.25		
<i>3-month follow-up</i>				
PE	8.329	7.50–9.16	ns	ns
MET	8.856	8.41–9.39		
<i>6-month follow-up</i>				
PE	7.583	7.09–8.08	ns	ns
MET	8.513	8.07–8.84		
<i>12-month follow-up</i>				
PE	8.843	7.57–10.18	ns	ns
MET	9.450	8.42–10.48		

Δ =1 CV of mean of PE and MET at baseline

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Clinically significant change in individual data. Three PE (Cases 1, 6 and 8) and four MET (Cases 10, 11, 12 and 18) participants had clinically significant decreases in HbA1c post-intervention (Figure 1). For the PE participants the decrease in HbA1c tended to be maintained to six month follow-up. In contrast, there appeared to be continued improvements in the MET participants' HbA1c, such that at 3- and 6-month follow-up five MET participants had further clinically significant decreases in HbA1c, although these changes were not maintained at 12-month follow-up.

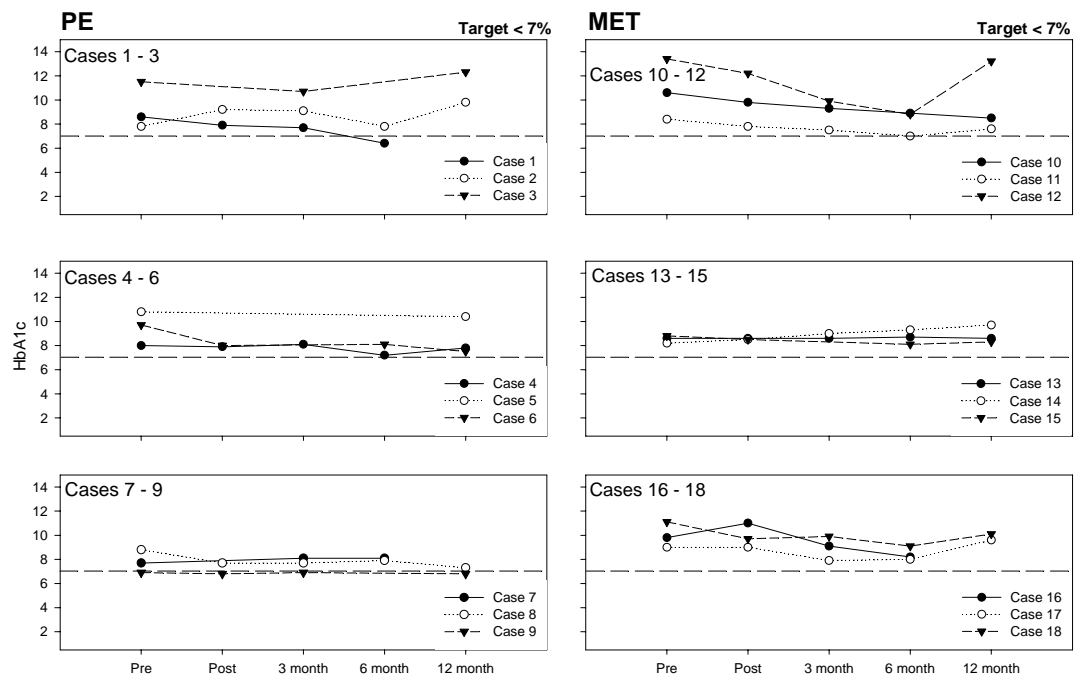


Figure 1. Average blood glucose

Self-monitored blood glucose data. Two PE participants (Cases 7 and 8) did not engage in SMOBG at baseline, limiting conclusions that can be drawn, and mixed results from the remaining PE participants (Figure 2, Table 7). There was a decrease in self-monitored blood glucose during PE for three participants (Cases 2, 4, and 9), with Cases 4 and 9 obtaining blood glucose results with-in the target range. Yet, another three participants (Cases 3, 5, and 6) had an increase in blood glucose during PE.

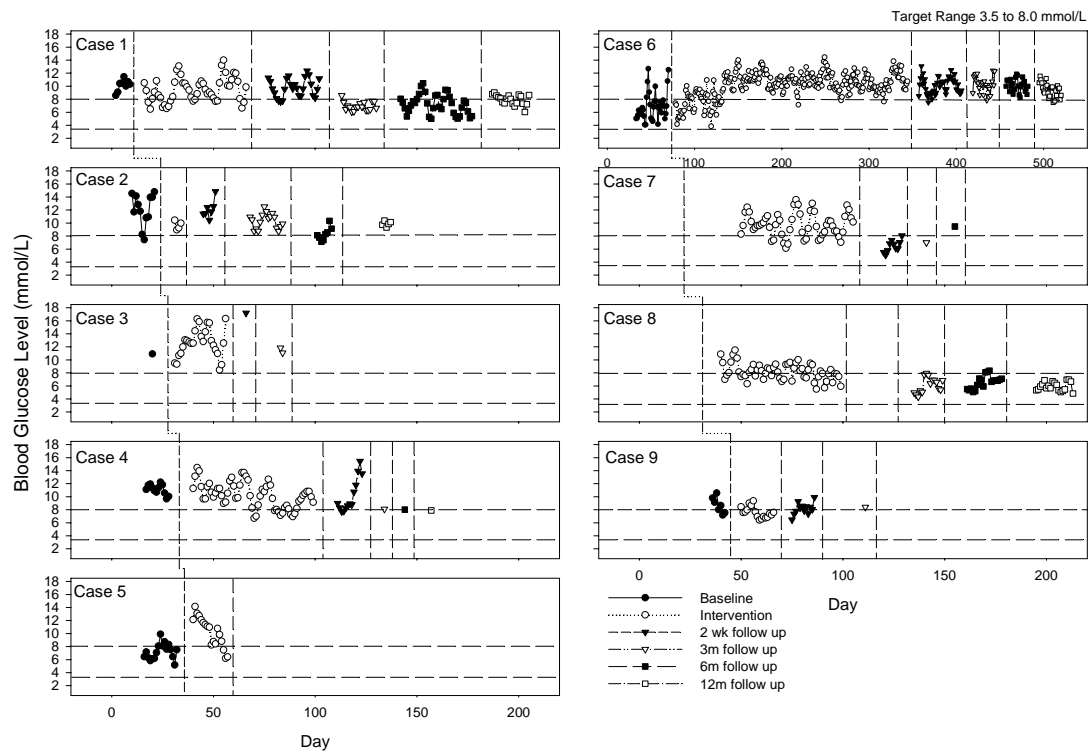


Figure 2. Results from SMOBG - PE

In four PE participants (Cases 1, 2, 4, and 8), however, self-monitored blood glucose appeared to be lower at 3-months compared to baseline. Furthermore, for four of the five PE participants for whom 12-month follow-up data are available, it appears that the decreases in self-monitored blood glucose were maintained.

Table 7. Means and standard deviations of self-monitored blood glucose level during baseline, intervention, post-intervention and follow-up – PE and MET

		Baseline	Intervention	2 wk follow-up	3 mnth follow-up	6 mnth follow-up	12 mnth follow-up
<i>PE</i>							
Case 1	<i>Mean</i>	10.11	9.45	9.78	6.94	7.22	7.92
	<i>SD</i>	0.91	1.88	1.39	0.67	1.57	0.78
Case 2	<i>Mean</i>	12.09	9.64	12.12	10.30	8.34	9.88
	<i>SD</i>	2.42	0.68	1.39	1.16	1.03	0.41
Case 3	<i>Mean</i>	10.9	12.66	17.2	11.45		
	<i>SD</i>	-	2.23	-	0.54		
Case 4	<i>Mean</i>	11.12	10.22	10.22	8.1	8.0	7.9
	<i>SD</i>	0.78	1.97	2.62	-	-	-
Case 5	<i>Mean</i>	7.20	10.23				
	<i>SD</i>	1.20	2.33				
Case 6	<i>Mean</i>	6.88	10.14	10.10	10.32	10.13	9.4
	<i>SD</i>	2.15	1.94	1.22	1.19	0.98	1.10
Case 7	<i>Mean</i>		9.72	6.46	7.0	9.47	
	<i>SD</i>		1.83	0.91	-	-	
Case 8	<i>Mean</i>		8.18		6.15	6.59	5.95
	<i>SD</i>		1.28		1.19	1.01	0.68
Case 9	<i>Mean</i>	8.69	7.58	8.15	8.4		
	<i>SD</i>	1.23	0.87	0.90	-		
<i>MET</i>							
Case 10	<i>Mean</i>	9.48	10.00	10.96	7.35		9.12
	<i>SD</i>	4.87	3.95	3.66	2.81		2.15
Case 11	<i>Mean</i>		7.50	7.99	8.27	10.42	
	<i>SD</i>		2.58	2.04	2.67	3.43	
Case 12	<i>Mean</i>	17.43	17.40	14.57	14.36	12.83	18.91
	<i>SD</i>	3.48	3.95	3.70	2.88	2.14	2.37
Case 13	<i>Mean</i>	9.73	9.66	9.57	12.03	14.39	9.45
	<i>SD</i>	2.52	2.52	2.29	1.77	1.48	2.77
Case 14	<i>Mean</i>	11.2	7.99	8.16	10.94	10.13	8.83
	<i>SD</i>	-	1.06	2.28	1.06	1.65	1.26
Case 15	<i>Mean</i>	9.93	7.75	8.19	7.75	9.00	8.64
	<i>SD</i>	1.63	2.22	2.18	1.27	1.90	2.43
Case 16	<i>Mean</i>	18.1	13.44		15.47	7.61	11.47
	<i>SD</i>	-	2.77		3.44	0.81	-
Case 17	<i>Mean</i>	11.2	9.74	9.69	9.07	7.80	
	<i>SD</i>	1.61	1.63	1.63	0.81	1.49	
Case 18	<i>Mean</i>	13.37	8.81	7.57	9.02	8.7	9.55
	<i>SD</i>	3.88	3.55	2.54	2.73	-	2.29

Only one MET participant (Case 11) did not engage in SMOBG at baseline, although baseline data were also limited for two other MET participants (Cases 14 and 16). The results, however, suggest that there was a downward trend in self-monitored blood glucose during MET for five (Cases 14, 15, 16, 17 and 18) of the MET participants, four (Cases 15, 16, 17 and 18) of whom obtained blood glucose results in the target range (Figure 3, Table 7). In contrast to PE, no MET participants showed an increase in self-monitored blood glucose during MET. Furthermore, although the results fluctuated over time (between and within participants), at least six of the MET participants had lower self-monitored blood glucose at 12-month follow-up.

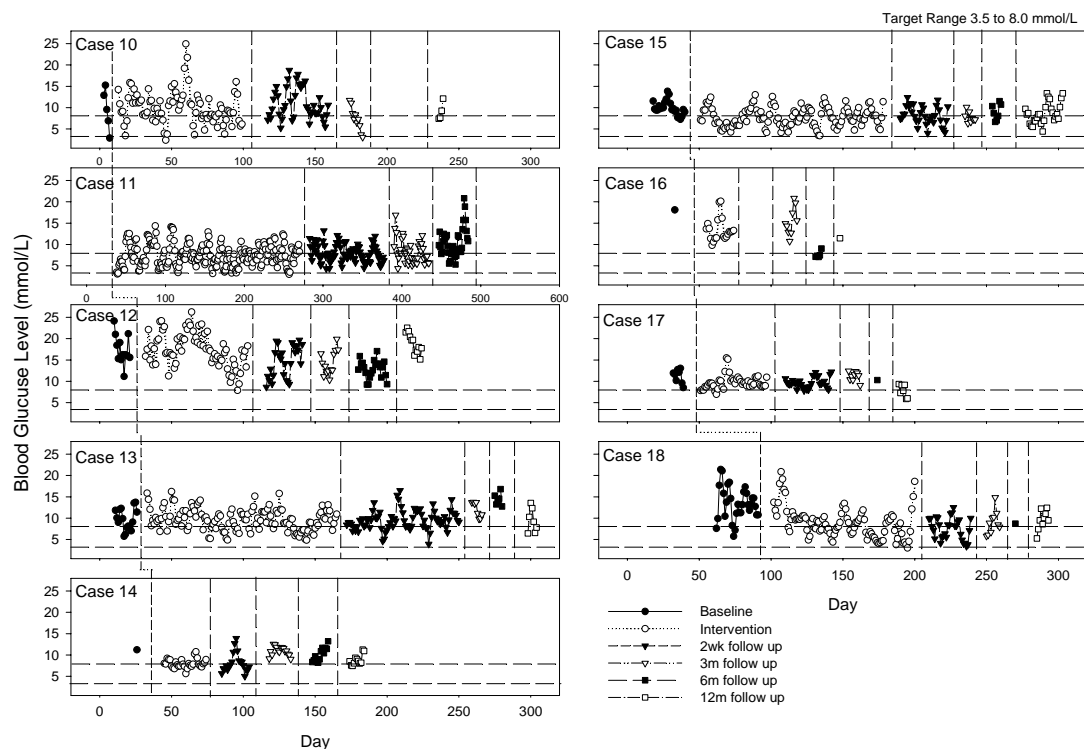


Figure 3. Blood glucose results from SMOBG – MET

It therefore appears that MET may have contributed to a decrease in blood glucose as measured by SMOBG, which tended to be maintained during follow-up. In contrast, the data do not support PE having a positive effect on blood glucose, with mixed results obtained during PE (i.e., an equal number showed improvements in self-monitored blood glucose as showed a deterioration), although four of the PE participants had lower self-monitored blood glucose at 3- and 12-month follow-up.

Lipids

Statistical tests of group data. Most PE lipid results were not statistically equivalent but were also not statistically different to baseline (Table 8), resulting in statistical indeterminacy. A statistically significant difference was, however, obtained for triglycerides from baseline to post-intervention and baseline to 12-month follow-up, with statistically significant decreases in triglycerides, and moderate to large effect sizes ($d=.88$ post-PE and $d=.58$ at 12-month follow-up) in both instances. This suggests that the participants' triglycerides decreased post-PE and that this decrease, whilst fluctuating over the follow-up period, was maintained at 12-month follow-up.

Table 8. Lipid means, inferential confidence intervals and results of statistical tests – PE

Time	Mean	r	95% CI	Different	Equivalent
<i>Total cholesterol</i>					$\Delta = .91$
Baseline	5.575		5.153–5.997		
Post-intervention	5.540	.9421	4.513–5.692	ns	ns
Baseline	5.575		5.131–6.019		
3-month follow-up	5.757	.6717	5.290–6.224	ns	ns
Baseline	5.575		5.185–5.965		
6-month follow-up	5.017	.7840	4.448–5.585	ns	ns
Baseline	5.575		5.116–6.035		
12-month follow-up	5.271	.6556	4.730–5.813	ns	ns
<i>Triglycerides</i>					$\Delta = .96$
Baseline	3.085		2.491–3.684		
Post-intervention	1.920	.71381	1.469–1.965	*	ns
Baseline	3.085		2.725–3.450		
3-month follow-up	3.071	.8721	2.741–3.402	ns	ns
Baseline	3.085		2.418–3.757		
6-month follow-up	2.117	.6949	1.728–2.505	ns	ns
Baseline	3.085		2.689–3.486		
12-month follow-up	2.314		1.945–2.684	*	ns
<i>HDL cholesterol</i>					$\Delta = .30$
Baseline	1.101		.928–1.274		
Post-intervention	1.060	.9379	.955–1.166	ns	ns
Baseline	1.101		.900–1.303		
3-month follow-up	1.021	.8358	.910–1.133	ns	ns
Baseline	1.101		.876–1.326		
6-month follow-up	1.093	.7250	.963–1.223	ns	ns
Baseline	1.101		.896–1.307		
12-month follow-up	1.117	.8877	1.018–1.216	ns	*
<i>LDL cholesterol</i>					$\Delta = 1.29$
Baseline	5.017		4.588–5.445		
Post-intervention	5.080	.7457	4.658–5.502	ns	*
Baseline	5.017		4.532–5.501		
3-month follow-up	5.200	.7060	4.580–5.820	ns	*
Baseline	5.017		4.621–5.413		
6-month follow-up	4.583	.7862	4.232–4.935	ns	*
Baseline	5.017		4.350–5.776		
12-month follow-up	4.386	.2299	3.884–4.888	ns	ns
<i>Risk ratio</i>					$\Delta = 1.0\%$
Baseline	3.786		3.208–4.303		
Post-intervention	3.600	.9856	3.190–4.010	ns	ns
Baseline	3.786		3.328–4.243		
3-month follow-up	4.257	.9407	3.818–4.696	ns	ns
Baseline	3.786		3.034–4.577		
6-month follow-up	3.000	.8384	3.500–5.015	ns	ns
Baseline	3.786		2.986–4.595		
12-month follow-up	3.529	.8892	2.992–4.065	ns	ns

r=Pearson's correlation

 Δ =1 CV of PE baseline mean

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Statistically equivalent results were obtained for HDL cholesterol between baseline and 12-month follow-up, suggesting that at 12-month follow-up the participants' HDL cholesterol had increased such that it was equivalent to baseline. LDL cholesterol results post-intervention and at 3- and 6-month follow-up were statistically equivalent to baseline, but not at 12-month follow-up. This suggests that there had been a decrease in LDL cholesterol at 12-month follow-up, but the decrease was not large enough to be statistically different to baseline, resulting in statistical indeterminacy.

Most MET lipid results were not statistically equivalent, but also not statistically different to baseline (Table 9), resulting in statistical indeterminacy. Statistically significant differences, however, were obtained for total cholesterol and LDL cholesterol which were both significantly lower than baseline at 12-month follow-up, with large effect sizes ($d=.81$ for total cholesterol and $d=.79$ for LDL cholesterol). This suggests that there had been a decrease in the MET participants' total cholesterol and LDL cholesterol from baseline to 12-month follow-up.

Statistically equivalent results were obtained for triglycerides from baseline to 12-month follow-up, HDL cholesterol from baseline to 3-month follow-up, and LDL cholesterol at 3- and 6-month follow-up. The risk ratio was also statistically equivalent from baseline to post-intervention through to 6-month follow-up, but at 12-month follow-up the risk ratio had decreased such that it was no longer statistically equivalent to baseline. The difference, however, was not statistically significant at the .05 level.

Table 9. Lipid means, inferential confidence intervals and results of statistical tests – MET

Time	Mean	r	95% CI	Different	Equivalent
<i>Total cholesterol</i>					$\Delta = .85$
Baseline	5.957		5.638–6.277		
Post-intervention	5.267	.9275	4.812–5.722	ns	ns
Baseline	5.957		5.499–6.415		
3-month follow-up	5.338		4.855–5.820	ns	ns
Baseline	5.957		5.557–6.346		
6-month follow-up	5.488	.8445	5.177–5.798	ns	ns
Baseline	5.957		5.430–6.484		
12-month follow-up	5.014	.7211	4.623–5.406	*	ns
<i>Triglycerides</i>					$\Delta = 1.15$
Baseline	2.586		1.116–4.056		
Post-intervention	1.6	.4007	.883–2.317	ns	ns
Baseline	2.586		1.196–3.976		
3-month follow-up	2.188	.4312	1.476–2.899	ns	ns
Baseline	2.586		1.369–3.802		
6-month follow-up	2.188	.9144	1.782–2.593	ns	ns
Baseline	2.586		2.396–2.775		
12-month follow-up	2.286	.9961	2.120–2.451	ns	*
<i>HDL cholesterol</i>					$\Delta = .22$
Baseline	1.541		.937–2.146		
Post-intervention	1.918	.8433	1.110–2.727	ns	ns
Baseline	1.541		1.473–1.610		
3-month follow-up	1.510	.9847	1.452–1.568	ns	*
Baseline	1.541		1.369–1.714		
6-month follow-up	1.563	.8856	1.414–1.711	ns	ns
Baseline	1.541		1.408–1.672		
12-month follow-up	1.447	.8731	1.342–1.553	ns	ns
<i>LDL cholesterol</i>					$\Delta = 1.14$
Baseline	4.417		3.732–5.109		
Post-intervention	3.500	.5811	2.869–4.131	ns	ns
Baseline	4.417		4.016–4.818		
3-month follow-up	4.200	.8580	3.846–4.555	ns	*
Baseline	4.417		4.109–4.725		
6-month follow-up	4.700	.9680	4.305–5.095	ns	*
Baseline	4.417		4.015–4.318		
12-month follow-up	3.550	.9324	3.282–3.818	*	ns
<i>Risk ratio</i>					$\Delta = 1.0\%$
Baseline	3.667		3.638–3.958		
Post-intervention	3.800	.9630	3.379–4.221	ns	*
Baseline	3.667		3.414–3.919		
3-month follow-up	3.729	.9563	3.416–4.042	ns	*
Baseline	3.667		3.504–3.829		
6-month follow-up	3.663	.9684	3.510–3.816	ns	*
Baseline	3.667		3.183–4.151		
12-month follow-up	2.780	.7290	2.340–3.220	ns	ns

r=Pearson's correlation

 Δ =1 CV of MET baseline mean

*=clinically significant at .05 level

ns=not statistically significant at .05 level

Lipid results for PE participants and MET participants were not statistically equivalent at baseline and throughout the study (Table 10). The difference, however, was not large enough to be statistically significant, resulting in statistical indeterminacy.

Table 10. Lipid means, inferential confidence intervals and results of statistical tests - PE vs MET

	Mean	95% CI	Different	Equivalent
Cholesterol				$\Delta=.88$
<i>Baseline</i>				
PE	5.575	4.796–6.354		
MET	5.957	5.015–6.899	ns	ns
<i>Post-intervention</i>				
PE	5.540	3.427–7.653		
MET	5.267	3.775–6.758	ns	ns
<i>3-month follow-up</i>				
PE	5.757	4.937–6.577		
MET	5.388	4.330–6.430	ns	ns
<i>6-month follow-up</i>				
PE	5.017	3.873–6.160		
MET	5.488	4.728–6.247	ns	ns
<i>12-month follow-up</i>				
PE	5.271	4.350–6.193		
MET	5.014	4.312–5.716	ns	ns
Triglycerides				$\Delta=1.06$
<i>Baseline</i>				
PE	3.085	2.075–4.100		
MET	2.586	0.940–4.231	ns	ns
<i>Post-intervention</i>				
PE	1.920	1.118–2.668		
MET	1.600	0.790–2.410	ns	ns
<i>3-month follow-up</i>				
PE	3.071	2.172–3.971		
MET	2.188	1.340–3.035	ns	ns
<i>6-month follow-up</i>				
PE	2.117	1.545–2.689		
MET	2.188	1.635–3.521	ns	ns
<i>12-month follow-up</i>				
PE	2.314	1.546–3.083		
MET	2.286	0.763–3.809	ns	ns
HDL cholesterol				$\Delta=.26$
<i>Baseline</i>				
PE	1.101	0.759–1.444		
MET	1.541	1.093–1.990	ns	ns

	Mean	95% CI	Different	Equivalent
<i>Post-intervention</i>				
PE	1.060	0.828–1.292		
MET	1.918	1.249–2.588	ns	ns
<i>3-month follow-up</i>				
PE	1.021	0.822–1.401		
MET	1.570	1.110–1.911	ns	ns
<i>6-month follow-up</i>				
PE	1.093	0.885–1.302		
MET	1.563	1.156–1.969	ns	ns
<i>12-month follow-up</i>				
PE	1.117	0.943–1.299		
MET	1.447	1.083–1.811	ns	ns
LDL cholesterol				$\Delta = 1.22$
<i>Baseline</i>				
PE	5.017	4.167–5.866		
MET	4.417	3.349–5.479	ns	ns
<i>Post-intervention</i>				
PE	5.080	4.243–5.917		
MET	3.500	2.521–4.479	ns	ns
<i>3-month follow-up</i>				
PE	5.200	4.118–6.282		
MET	4.200	3.265–5.136	ns	ns
<i>6-month follow-up</i>				
PE	4.583	3.796–5.371		
MET	4.700	3.912–5.488	ns	ns
<i>12-month follow-up</i>				
PE	4.386	3.825–4.946		
MET	3.550	2.843–4.257	ns	ns
Risk ratio				$\Delta = 1.0\%$
<i>Baseline</i>				
PE	3.786	1.800–5.772		
MET	3.667	2.699–4.634	ns	ns
<i>Post-intervention</i>				
PE	3.600	2.123–5.077		
MET	3.800	2.485–5.115	ns	ns
<i>3-month follow-up</i>				
PE	4.257	2.422–6.092		
MET	3.729	2.574–4.883	ns	ns
<i>6-month follow-up</i>				
PE	3.000	2.029–3.971		
MET	3.663	2.813–4.512	ns	ns
<i>12-month follow-up</i>				
PE	3.529	2.235–4.822		
MET	2.780	1.925–3.636	ns	ns

r=Pearson's correlation

Δ = 1CV of mean of PE and MET at baseline

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Clinically significant change in individual data. Lipid results for the PE participants showed little change, with only one PE participant's (Case 8) lipid profile showing improvements consistent with improved blood glucose (Figures 4-8). Three MET participants (Case 10, 11, and 12), however, had improvements in their lipid profiles, consistent with improved blood glucose (Figures 4-8).

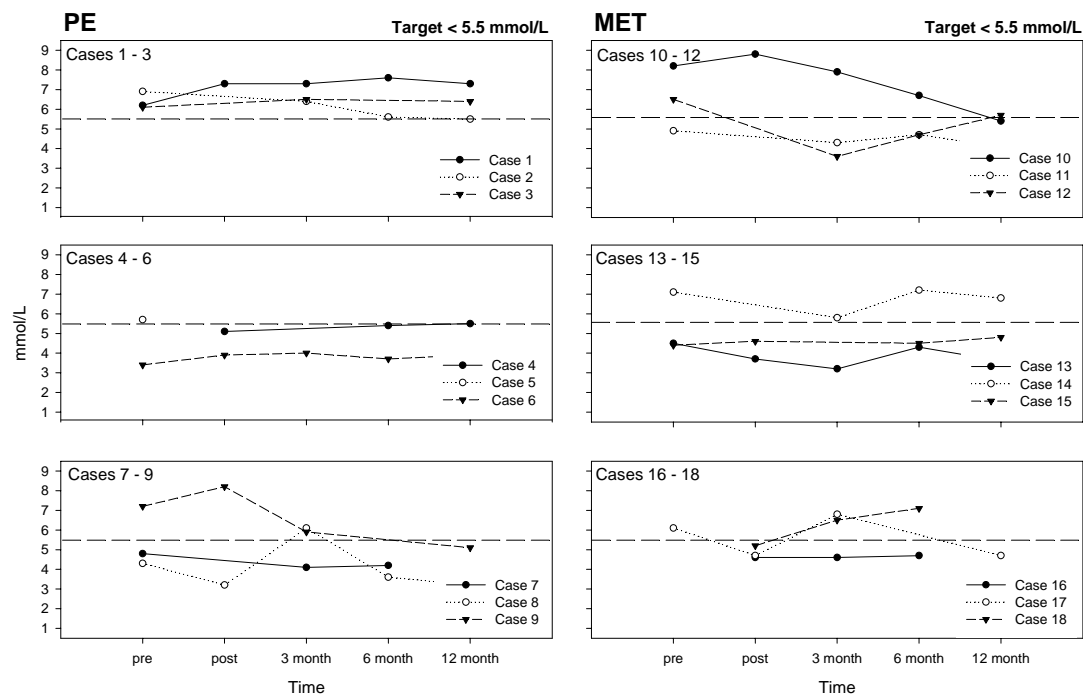


Figure 4. Total cholesterol

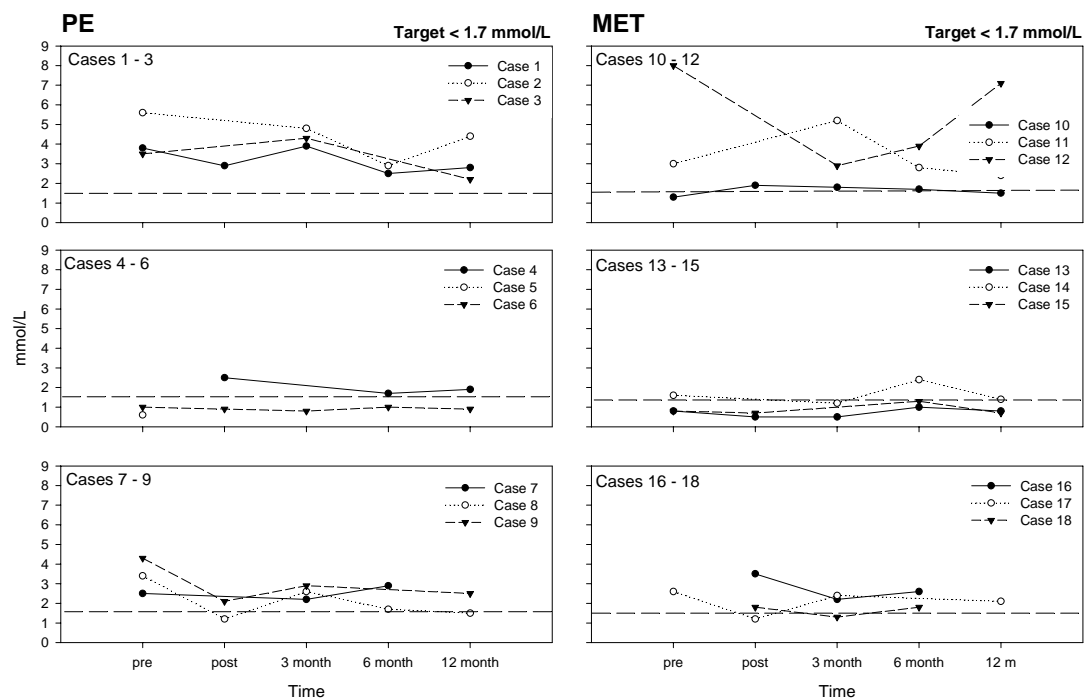


Figure 5. Tryglicerides

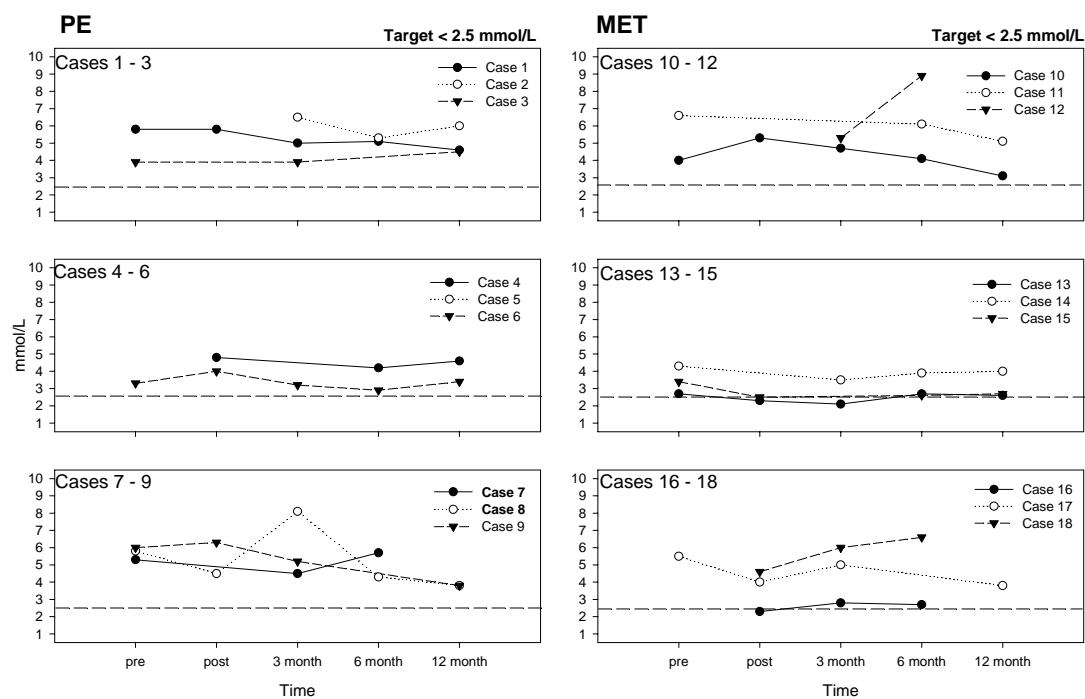


Figure 6. LDL cholesterol

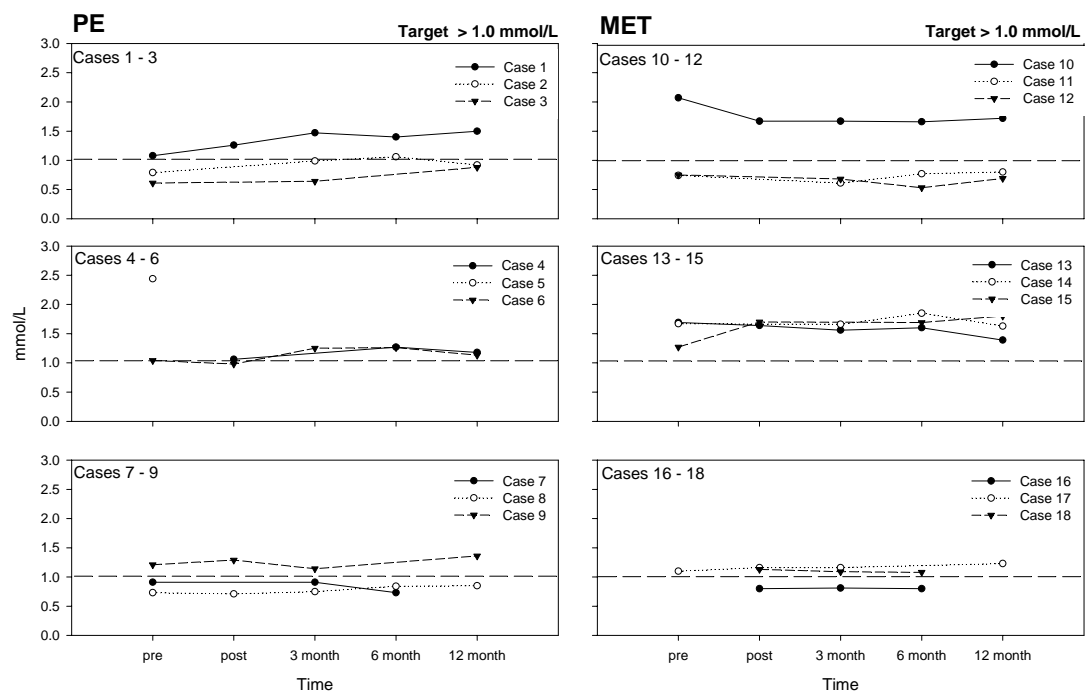


Figure 7. HDL cholesterol

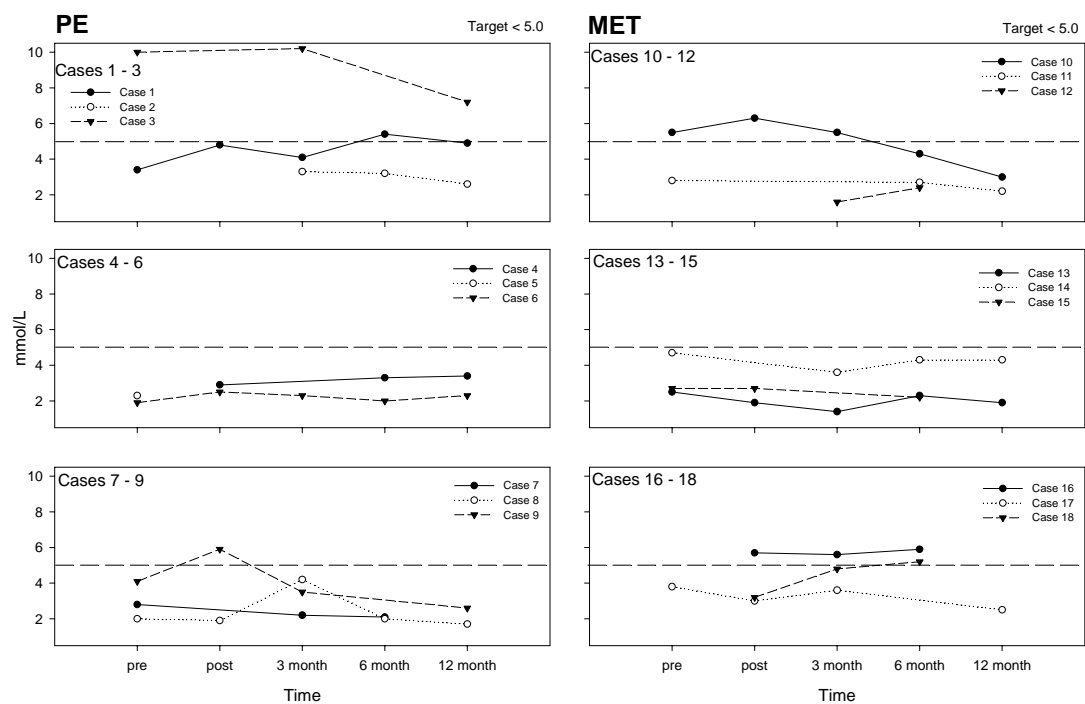


Figure 8. Risk ratio

Intermediate process variables

Diabetes self-management behaviour

SMOGB. Only one (Case 8) of the three PE participants who selected increased SMOGB as a treatment goal was able to achieve the target set (Figure 9). While the frequency of SMOGB was higher than at baseline (during which he did not engage in SMOGB), he was not able to maintain his target of four tests per day at 3-, 6- or 12-month.

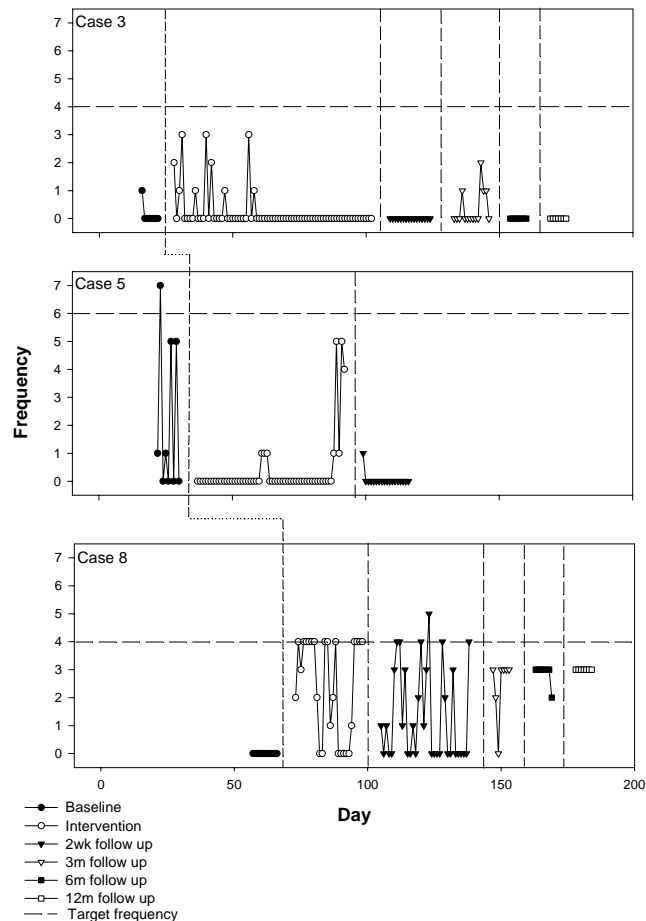


Figure 9. Self-management goal: Increase SMOGB – PE

Although Case 3 was not able to achieve the target of SMOBG four times per day three days per week, it appears that during PE there was an initial increase in frequency of SMOBG. This, however, was not maintained, with no testing occurring from approximately one month into PE and during follow-up, although some SMOBG did occur at 3-month follow-up.

In contrast, not only was Case 5 not able to achieve her target of engaging in SMOBG six times per day, the frequency of SMOBG appears to have decreased during PE. SMOBG occurred on approximately 55% of the days during baseline, and on one day in which the target of six times per day was achieved (actually exceeded), but only occurred on 14% of days during PE and on one day only during 2-week follow-up. Unfortunately, longer term follow-up data are not available.

Therefore, there is no evidence to support PE as having an effect (either positive or negative) on the participants' SMOBG. In contrast in Figure 10, there is evidence that MET contributed to an increase in SMOBG, which was typically maintained until at least 3-month follow-up (and up to 6- and 12-month follow-up in some instances). While there was an increase in the frequency in SMOBG with MET, it was not always to the target level set by each participant.

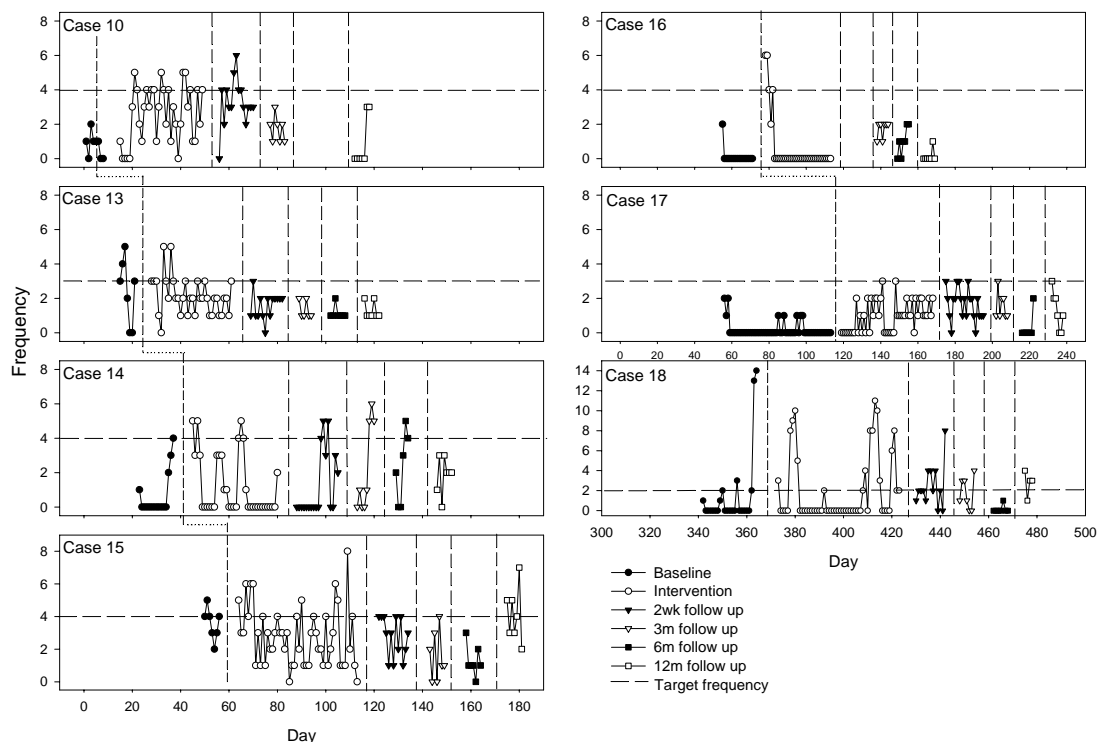


Figure 10. Self-management goal: increase SMOBG – MET

For example, Case 10, whose target was to engage in SMOBG four times per day, increased SMOBG from a mean of once (range 0-2) per day during baseline to a mean of three (range 0-5) times per day during MET. While he did not reach his target of four tests per day at 3-month follow-up, the level of SMOBG at 3-month follow-up was still higher than at baseline, with a mean of two tests per day (range 1-3). SMOBG, however, was not occurring at 6-month follow-up and was variable at 12-month follow-up.

Case 17, whose goal was to increase SMOBG to three times per day twice a week, was infrequently engaging in SMOBG during baseline. She increased the frequency of SMOBG during MET, testing on more than 50% of days, and tested three times on two days. There appears to have been a further increase in the overall frequency of SMOBG at 2-week and 3-month follow-up, with testing occurring 93%

and 100% of days at 2-week and 3-month follow-up respectively. Although at 6-month follow-up there was a decrease towards baseline, the frequency of SMOBG increased again at 12-month follow-up to 71% of days in which testing occurred, but still not to the target level.

Similarly, at baseline Case 18 was meeting (or exceeding) his target of testing twice per day on less than a third of days and was not engaging in SMOBG at all on approximately two-thirds of days during baseline. During MET there was an increase in the frequency of SMOBG, with more days in which he met (or exceeded) his target, although there were still periods during MET in which he tended not to engage in SMOBG. During 2-week follow-up, the frequency of SMOBG increased to 85% of days in which some SMOBG occurred, and the target of testing twice per day was achieved on 69% of the days. This increase in SMOBG, however, does not appear to have been maintained at 3-month and 6-month follow-up, with a return to baseline levels of SMOBG at 6-month follow-up. Yet, at 12-month follow-up SMOBG occurred on most days and was at or above the target level.

Case 16 was not meeting his target of engaging in SMOBG four times per day at all during baseline, and in fact had only one day during baseline in which he engaged in SMOBG. While he achieved (or exceeded) the target on most days in the initial stages of MET, he did not maintain this improvement, with no SMOBG for the remainder of MET. At 3- and 6-month follow-up, however, he was engaging in SMOBG most days, although not at his target level.

Data from SMOBG suggests considerable variability (ranging from 0-6 times per day) in the frequency of SMOBG throughout the study for Case 14. She, however, achieved her goal of testing four times a day on 14% of days during MET compared to only 6% (one day) during baseline. The increase in SMOBG, however, may not be solely attributable to the effect of MET as there appears to have been an upward trend during baseline, suggesting that she was already starting to increase her SMOBG prior to MET. The increased SMOBG appears to have been maintained during 2-week follow-up (testing four times per day on 16% of days) and to have increased at 3- and 6-month follow-up, with SMOBG occurring four times per day on 38% and 33% of days, respectively. There appears to have been a trend towards baseline levels at 12-month follow, with no days in which SMOBG occurred four times, although at 12-month follow-up there was only one day in which no testing occurred, compared to no testing on the majority (73%) of days during baseline.

The evidence, however, for the effectiveness of MET in increasing SMOBG was less clear for two MET participants. Both participants were already achieving their target frequency for SMOBG at baseline. Case 13 was achieving her goal of engaging in SMOBG three times per day 57% of the time during baseline, but she appears to have had less success achieving this target during MET and follow-up. During MET and follow-up, however, there were fewer days in which no testing at all occurred, with no SMOBG on 29% of days in baseline, and only 3% and 7% during MET and for the two weeks post-MET, and SMOBG was occurring on a daily basis at 3-, 6- and 12-month follow-up.

Similarly, while Case 15 was already meeting or exceeding her target of engaging in SMOBG four times per day on 57% of days during baseline, she does not appear to have increased the frequency of her SMOBG during MET or follow-up. There were some days, however, during MET and at 12-month follow-up in which she exceeded her target of testing four times per day, testing 5-8 times in a day, whereas this occurred only once in baseline. Despite this, it appears that the number of days in which the target of testing four times a day decreased over the course of the study, such that at 6-months follow-up she was not meeting her target at all, although at 12-month follow-up the frequency of SMOBG appears to be higher than at baseline.

Thus, MET appears to have contributed to increased SMOBG for most, but not all, participants for whom this was a goal. The increase in SMOBG, however, was not always to the target frequency and did not tend to be maintained beyond 3-month follow-up.

Exercise. The data support MET as a means of increasing participants' exercise, with both MET participants who selected increased exercise as a goal being able to do so during MET (Figure 11). In contrast, the data do not support PE as a means of increasing exercise, with only one PE participant (Case 2) increasing her exercise, although not to the target level, during PE. Furthermore, the data suggests a decline in the other PE participant's exercise during PE.

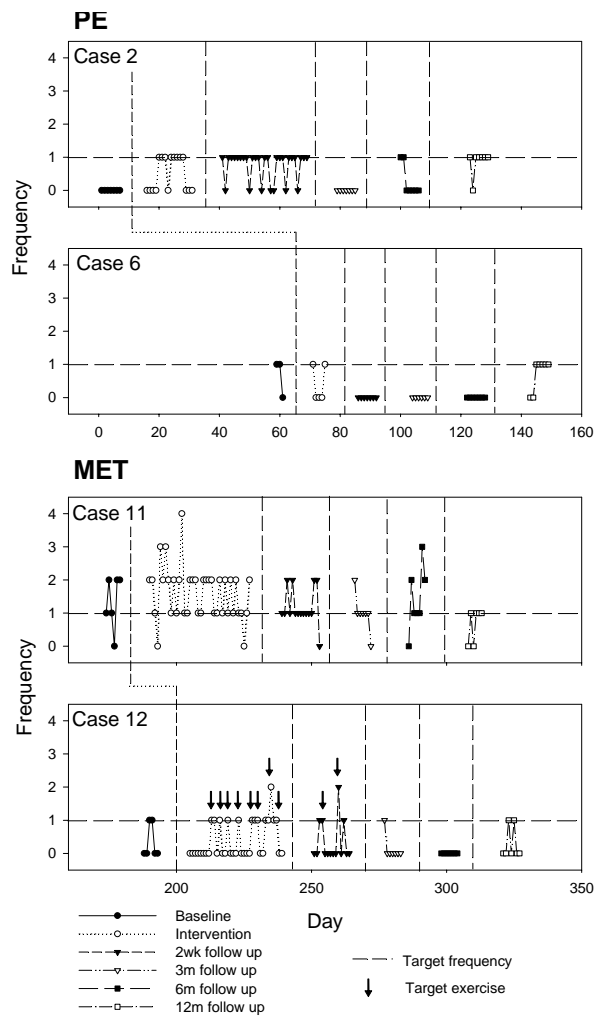


Figure 11. Self-management goal: increase exercise

Case 2's goal was to increase exercise to at least once per day, which she appears to have partially achieved during PE, with a 50% success rate. While she appears to have been meeting her target more frequently at 2-week follow-up, this was not maintained at 3- and 6-month follow-up, although at 12-month follow-up her exercise level appears to have increased to near target level.

Although Case 6 appeared to be already close to achieving her target of exercising once per day at baseline, there does not appear to have been an increase in exercise during PE, with the data suggesting a possible decline in the frequency of

exercise during PE. Furthermore, during 2-week follow-up she appears to have stopped exercising, and this appears to have been maintained at 3- and 6-month follow-up, although the frequency of exercise appears to have returned to baseline at 12-month follow-up.

In contrast, while Case 11 was already achieving, or exceeding, his exercise target most (i.e., 83%) days during baseline, he appears to have further increased his exercise during MET, meeting or exceeding his target on 95% of the days (i.e., missing his target on only two days during MET). Additionally, the mean number of exercise activities engaged in per day rose from baseline of one per day to two per day during MET. The gains made during MET appear to have been maintained during 2-week follow-up, with 93% of days in which he met or exceeded the target. At 3- and 6-month follow-up, however, the level of exercise appears to have returned to the baseline level, and at 12-month follow-up exercise appears to have decreased to below baseline.

Similarly, it appears that Case 12 was also able to achieve, and exceed, his goal to increase his exercise by attending a water-based exercise programme once per week during MET, attending the exercise programme twice per week, compared to not at all during baseline. There also appears to have been an increase in his level of exercise in general during MET, with exercise occurring on 46% of days after the first week of MET, compared to 33% at baseline. While he was still meeting his target of attending the exercise programme once per week during two-week follow-up, this was not maintained at 3-, 6- or 12-month follow-up, and his general level of exercise returned to baseline level.

Thus, MET also appears to have been a more effective intervention than PE for increasing exercise. Both MET participants who selected increased exercise as their self-management goal increased their exercise to or above target during MET. The increases in exercise, however, do not appear to have been maintained beyond 2-week follow-up.

Dietary compliance. The data do not support PE as a means of increasing dietary compliance (Figure 12). In contrast, the MET participants appear to have made improvements in dietary compliance during MET.

During PE there does not appear have been an improvement in dietary compliance for Case 7, with considerable variability (range 0-100% compliance) during PE. There, however, appears to have been an improvement in dietary compliance during 2-week follow-up, which was maintained throughout follow-up, with 41% compliance at baseline compared to 66% compliance during 2-week follow-up and again at 12-month follow-up, but there was still considerable variability (range 0-100%) in compliance. Because improvement in dietary compliance did not occur during PE, this change cannot be attributed to PE (i.e., some other factor may have contributed to this change).

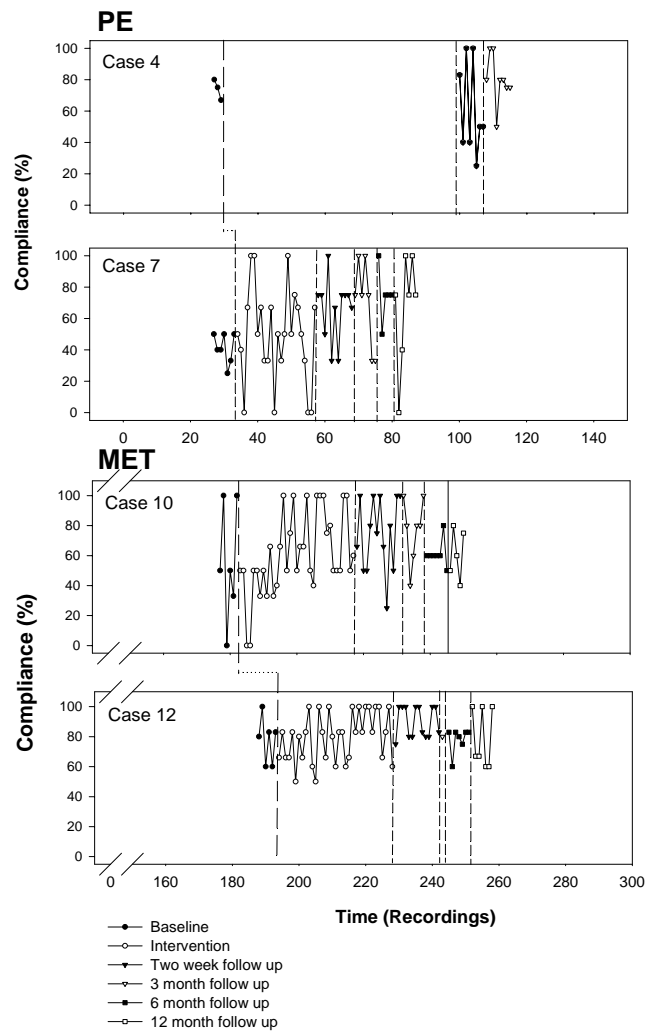


Figure 12. Self-management goal: dietary compliance

Further data in support of PE's effect on dietary compliance is not available, as Case 4 ceased monitoring her food intake during PE, preventing conclusions about the effect of PE on dietary compliance being drawn. The fact that Case 4 stopped self-monitoring, however, suggests that dietary compliance may not have been a focus and therefore may not have improved.

In contrast, dietary compliance for Case 10 improved from a mean of 56% at baseline to 68% during the last three weeks of MET. There appears to have been further improvements in dietary compliance at 2-week and 3-month follow-up (mean

of 74% and 77%, respectively). Furthermore, dietary compliance appears to have been maintained (although not at the level achieved earlier in follow-up) at 6- and 12-month follow-up, with a mean of 61%.

Similarly, Case 12 achieved 100% compliance on 50% of days in the last two weeks of MET, compared to only one day (16%) during baseline. There also appears to have been further improvement in dietary compliance during 2-week follow-up, with no days in which compliance fell below 75%. Unlike Case 10, the improvements, however, do not appear to have been maintained at 3- and 6-month follow-up. Yet, while there was considerable variability at 12-month follow-up, he still achieved 100% compliance on three out of the seven days at 12-month follow-up, compared to only one day at baseline.

Thus, MET appears to have contributed to increased dietary compliance. Additionally, unlike the SMOBG and exercise self-management goals, there is evidence that the improvements in dietary compliance (although diminishing) were maintained at 12-month follow-up.

Regular eating. The data on the effect of PE and MET on regular eating is not strong as there was only one participant from each intervention who selected regular eating as a goal (Figure 13). The PE participant (Case 7) does not appear to have achieved his goal of eating more regularly, with a small decline in meals/snacks during PE and 2-week follow-up, from a mean of four meals/snacks per day at baseline to three during PE and 2-week follow-up, although there were similar levels to baseline for the remainder of follow-up (Figure 13).

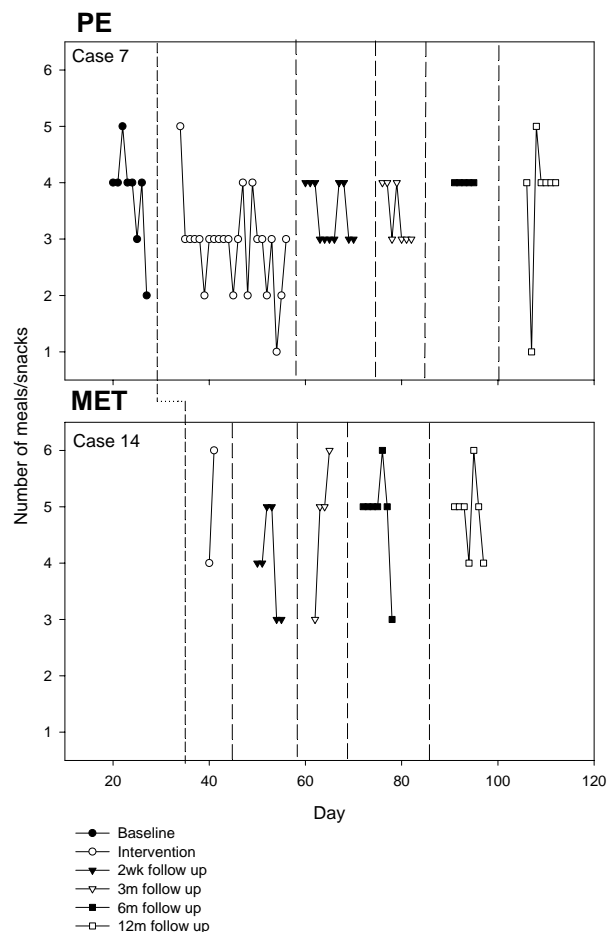


Figure 13. Self management goal: regular eating

Unfortunately, Case 14 did not keep a record of her eating during baseline and for most of MET, so conclusions about the effect of MET cannot be drawn. That she started keeping a record during MET and maintained this throughout follow-up, however, suggests that at least she had started focusing more on her eating.

Weight loss. Three participants (two PE and one MET) also selected weight loss as a goal. While the lack of multiple data points does not enable a true single-case design analysis, the results were still graphed for analysis (Figure 14). The data

suggests that neither intervention had any significant effect on the participants' weight.

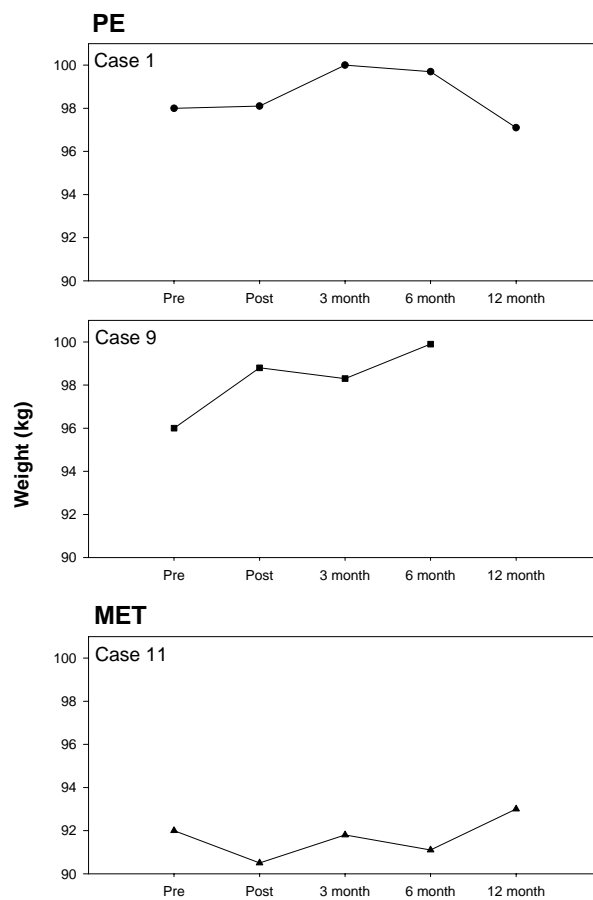


Figure 14. Self-management goal: weight loss

For example, Case 1's weight remained stable from baseline to post-PE, and then increased by 2kg at 3-month follow-up, although, her weight decreased at 12-month follow-up to below baseline. Case 9's weight increased from baseline to post-PE, and over the follow-up period.

While Case 11's weight was higher at 12-month follow-up than at baseline, his weight decreased by 1.5kg from baseline to post-MET. There, however, was not a sustained and continued weight loss over follow-up, with his weight fluctuating, but gradually increasing over this time.

Psychosocial measures

Statistical comparisons for each psychosocial measure are made within groups across time (i.e., PE and MET separately at baseline, post-intervention and 12-month follow-up), and between groups across time (i.e., PE compared to MET at baseline, post-intervention and 12-month follow-up). This is then followed by an evaluation of individual case data for PE and MET in terms clinically significant change.

Personal Models of Diabetes. PE Post-intervention and 12-month follow-up PMDI treatment effectiveness results were not statistically equivalent to baseline, but also were not statistically different, resulting in statistical indeterminacy (Table 11). The baseline scores tended to be lower, suggesting the participants tended to consider the TAU they received at baseline less effective than PE or the TAU they received at 12-month follow-up. Baseline treatment effectiveness results, however, were statistically equivalent to post-MET and 12-month follow-up (Table 11), suggesting that the participants considered the TAU they received at baseline as effective as MET and the TAU they received at 12-month follow-up.

Table 11. PMDI means, inferential confidence intervals and results of statistical tests – PE and MET

Time	Mean	r	95% CI	Different	Equivalent
PE					
<i>Treatment Effectiveness</i>					$\Delta=3.688$
Baseline	12.044		10.445–13.644		
Post-intervention	13.578	.6477	12.582–14.574	ns	ns
Baseline	12.044		9.761–14.328		
12-month follow-up	13.275	.1783	11.867–14.633	ns	ns
<i>Seriousness</i>					$\Delta=2.980$
Baseline	16.667		15.252–18.081		
Post-intervention	17.778	.7891	16.305–19.251	ns	ns
Baseline	16.667		13.691–19.643		
12 month follow-up	14.875	.0806	10.928–18.822	ns	ns
MET					
<i>Treatment Effectiveness</i>					$\Delta=3.688$
Baseline	14.417		13.630–15.203		
Post-intervention	15.856	.6582	15.063–16.648	ns	*
Baseline	14.417		13.724–15.109		
12-month follow-up	15.700	.7416	14.917–16.483	ns	*
<i>Seriousness</i>					* $\Delta=2.980$
Baseline	23.889		22.566–25.210		
Post-intervention	21.222	.5892	20.084–22.358	*	ns
Baseline	23.889		21.774–26.004		
12 month follow-up	22.556	-.0474	19.615–25.496	ns	ns

r=Pearson's correlation

$\Delta=1$ standard deviation of PE and MET at baseline

*=statistically significant at .05 level

ns=not statistically significant at .05 level

PE Baseline, post-intervention and 12-month follow-up scores for PMDI diabetes seriousness were also statistically indeterminate (Table 11). Post-PE seriousness scores tended to be higher than baseline and 12-month follow-up, suggesting that the PE participants tended to be more concerned about the seriousness of their diabetes, future complications, and the current consequences of diabetes after PE than at baseline or 12-month follow-up.

In contrast to the PE participants, the MET participants' post-intervention results on the seriousness of diabetes were lower and statistically different to baseline (Table 11), with a moderate effect size ($d=.62$). This suggests that MET participants were less concerned about the seriousness of their diabetes, future complications, and the current consequences of diabetes after MET. At 12-month follow-up, however, the MET diabetes seriousness results were statistically indeterminate. PE and MET treatment effectiveness results were also statistical indeterminate at baseline, post-intervention and at 12-month follow-up (Table 12).

At baseline, MET participants' ratings of the seriousness of their diabetes were statistically higher than the ratings of the PE participants (Table 12). This suggests that at baseline MET participants were more concerned about the current seriousness of their diabetes, future complications, and the effect on their lives. Post-intervention, however, the MET participants' concern about the seriousness of their diabetes had decreased to the extent that their scores were no longer statistically different to the PE participants, although the scores were also not statistically equivalent, resulting in statistical indeterminacy. This pattern was repeated at 12-month follow-up.

Table 12. PMDI means, inferential confidence intervals and results of statistical tests – PE vs MET

	Mean	95% CI	Different	Equivalent
Effectiveness:				$\Delta=3.688$
<i>Baseline</i>				
PE	12.044	9.543–14.546		
MET	14.417	13.019–15.815	ns	ns
<i>Post-intervention</i>				
PE	13.578	12.077–15.078		
MET	15.856	14.499–17.213	ns	ns
<i>12-month follow-up</i>				
PE	13.275	11.817–14.734		
MET	15.700	14.179–17.221	ns	ns
Seriousness:				$\Delta=2.980$
<i>Baseline</i>				
PE	16.667	13.530–19.803		
MET	23.889	21.806–25.972	*	ns
<i>Post-intervention</i>				
PE	17.778	14.439–21.117		
MET	21.222	19.390–23.048	ns	ns
<i>12-month follow-up</i>				
PE	14.875	10.741–19.009		
MET	22.556	19.678–25.434	*	ns

* $\Delta=1$ standard deviation of PE and MET at baseline

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Problem Areas in Diabetes. The PE participants' PAID baseline and post-intervention results were statistically equivalent (Table 13). This suggests that the PE participants' emotional adjustment to their diabetes remained unchanged (i.e., mean score suggesting a moderate level of diabetes-related distress) from baseline to post-PE. The 12-month follow-up results, however, were lower than, and statistically different to, baseline, with a large effect size ($d=.84$), suggesting that the PE participants' emotional adjustment to diabetes improved during follow-up (i.e., mean score suggesting a low level of diabetes-related distress).

Table 13. PAID means, inferential confidence intervals and outcome of statistical tests – PE and MET

Time	Mean	r	95% CI	Different	Equivalent ($\Delta=23.1$)
PE					
Baseline	34.531		8.529–43.138		
Post-intervention	27.309	.6994	22.084–35.127	ns	*
Baseline	34.531		25.409–46.250		
12-month follow-up	19.125	.5431	14.438–25.250	*	ns
MET					
Baseline	31.250		26.875–36.308		
Post-intervention	25.833	.5401	20.304–31.363	ns	*
Baseline	31.250		28.127–34.374		
12-month follow-up	23.722	.7789	19.545–27.433	*	*

r =Pearson's correlation

Δ =1 standard deviation from Welch et al (1997)

*=statistically significant at .05 level

ns=not statistically significant at .05 level

MET participants' scores on the PAID post-intervention were statistically equivalent to baseline (Table 13), suggesting that there was no change in participants' emotional adjustment to diabetes post-MET (i.e., mean score suggesting a moderate level of diabetes-related distress), similar to PE. At 12-month follow-up, however, the PAID results were lower (moderate effect size, $d=.60$, and a mean score suggesting a low level of diabetes-related distress) and statistically different to baseline, but were also statistically equivalent, resulting in statistical indeterminacy.

At baseline, PE and MET participants' PAID results were statistically indeterminate (Table 14). Post-intervention and at 12-month follow-up, however, PE and MET participants' PAID scores were statistically equivalent (Table 14), suggesting that both groups had similar emotional adjustment to their diabetes.

Table 14. PAID means, inferential confidence intervals and results of statistical tests – PE vs MET

	Mean	95% CI	Different	Equivalent ($\Delta=23.1$)
<i>Baseline</i>				
PE	34.531	21.828–49.838		
MET	31.250	24.558–37.941	ns	ns
<i>Post-intervention</i>				
PE	27.309	16.593–40.629		
MET	25.833	17.712–33.955	ns	*
<i>12-month follow-up</i>				
PE	19.531	12.970–26.717		
MET	23.722	15.725–31.719	ns	*

* $\Delta=1$ standard deviation from Welch et al (1997)

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Diabetes Knowledge Test. Statistically equivalent results were obtained on the DKT at baseline and post-intervention, and at 12-month follow-up for both PE and MET (Table 15). This suggests that there was no change in PE and MET participants' knowledge about diabetes during the course of the study.

Table 15. DKT means, inferential confidence intervals and outcome of statistical tests – PE and MET

Time	Mean	r	95% CI	Different	Equivalent ($\Delta=16.222$)
PE					
Baseline	60.111		55.390–64.843		
Post-intervention	62.667	.7837	58.319–67.014	ns	*
Baseline	60.111		54.354–65.868		
12-month follow-up	58.250	.7353	54.199–63.301	ns	*
MET					
Baseline	68.333		63.874–72.792		
Post-intervention	72.889	.6534	67.587–78.191	ns	*
Baseline	68.333		63.684–72.983		
12-month follow-up	75.444	.6645	72.223–78.666	ns	*

r=Pearson's correlation

$\Delta=1$ standard deviation of PE and MET sample

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Yet, PE and MET participants' DKT results were not statistically equivalent at baseline or post-intervention, with the MET participants tending to have greater diabetes knowledge (Table 16), although the results were not statistically different, resulting in statistical indeterminacy. At 12-month follow-up, however, the MET participants' scores were higher and statistically different to the PE participants' scores, suggesting that the MET participants' knowledge about diabetes at 12-month follow-up was greater than the PE participants' knowledge.

Table 16. DKT means, inferential confidence intervals, and results of statistical tests – PE vs MET

	Mean	95% CI	Different	Equivalent ($\Delta=16.222$)
<i>Baseline</i>				
PE	60.111	49.895–70.327		
MET	68.333	60.806–75.861	ns	ns
<i>Post-intervention</i>				
PE	62.667	53.382–71.952		
MET	72.889	64.036–81.744	ns	ns
<i>12-month follow-up</i>				
PE	58.250	51.066–65.434		
MET	75.444	70.231–80.657	*	ns

$\Delta=1$ standard deviation of PE and MET at baseline

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Clinically significant change. Most (n=6) of the PE participants considered PE to be as effective as the TAU they received at baseline and at 12-month follow-up (Table 17). Similarly, most (n=7) MET participants considered MET to be equally as effective as the TAU they received at baseline. Four participants (Case 10, 16, 17, and 18) who had received MET, however, considered the TAU they received at 12-month follow-up more effective than that received at baseline.

Table 17. Clinically significant change on the PMDI, PAID and DKT – PE and MET

	PMDI				PAID		DKT	
	<i>Treatment Effectiveness</i>		<i>Seriousness</i>		Post	12-month	Post	12-month
	Post	12-month	Post	12-month				
PE								
<i>Case 1</i>	+3.58	+5.69	+2.52	+3.52	-3.83	-2.62		+2.56
<i>Case 2</i>				-4.03				
<i>Case 3</i>				+3.02				
<i>Case 4</i>		-4.39		-2.52				
<i>Case 5</i>								
<i>Case 6</i>	+5.21			-10.07	-2.82	-3.62	+5.12	+3.84
<i>Case 7</i>	+5.12	+8.05			-2.22			
<i>Case 8</i>			-2.01	-2.01				
<i>Case 9</i>			+3.02		+3.22			
MET								
<i>Case 10</i>	+3.05	+2.97	-3.83	+4.03	-3.62			+2.38
<i>Case 11</i>				-2.01	+2.01			+2.38
<i>Case 12</i>			-2.01	-3.52	-3.02		+4.03	+3.29
<i>Case 13</i>			-2.52	-3.52		-2.82		-2.38
<i>Case 14</i>						-2.46	+4.03	
<i>Case 15</i>			-3.52	-4.53	-2.01	-3.22	+2.56	
<i>Case 16</i>		+2.55						+3.84
<i>Case 17</i>		+5.03						
<i>Case 18</i>	+3.74	+3.38					-2.38	

+ =clinically significant increase in score (i.e., RC>1.96) from baseline

- =clinically significant decrease in score (i.e., RC>1.96) from baseline

NB: empty cell means there was no clinically significant change in the score from baseline

Four MET participants (Case 10, 12, 13, and 15) appear to have had a decrease in concern about the seriousness of their diabetes post-MET and at 12-month follow-up (Table 17). In contrast, the majority (n=5) of PE participants' concern appears to have remained the same post-PE, with only one participant (Case 8) experiencing a decrease in concern post-PE and two (Case 1 and 9) experiencing an increase in concern. Yet three participants (Case 2, 4, and 6) experienced a decrease (from baseline) in concern at 12-month follow-up.

There appears to have been no change in emotional adjustment to diabetes (Table 17) for the majority of PE and MET participants post-intervention (PE n=6, MET n=5) and at 12-month follow-up (PE and MET n=7). Three PE (Case 1, 6 and 7) and MET (Case 10, 12, and 15) participants, however, did show an improvement in emotional adjustment to diabetes post-intervention, while one PE (Case 9) and MET (Case 11) appeared to have a deterioration in adjustment to diabetes post-intervention.

Similarly, there appears to have been no change in knowledge about diabetes for all but one PE participant (Case 6) post-PE and at 12-month follow-up (Table 17). In contrast, although there also appears to have been no change in their knowledge about diabetes for five MET participants, three (Case 12, 14 and 15) showed an increase in knowledge from baseline to post-MET and four (Case 10, 11, 12, and 16) at 12-month follow-up.

As Figure 15 shows, an equal number (n=4) of PE participants appear to have experienced an increase in motivation to change as experienced a decrease post-PE. In contrast, the majority (n=6) of MET participants appear to have had an increase in motivation, with only one MET participant's motivation decreasing post-MET. Most of the PE and MET participants whose motivation to change appears to have increased (typically to the action stage of change) following intervention, were in the preparation stage of change at baseline, suggesting that they were ready to engage in behaviour change at baseline and then moved to actual behaviour change post-intervention. The four PE participants whose motivation to change appears to have decreased following intervention were spread between the contemplation, action and maintenance stages of change at baseline.

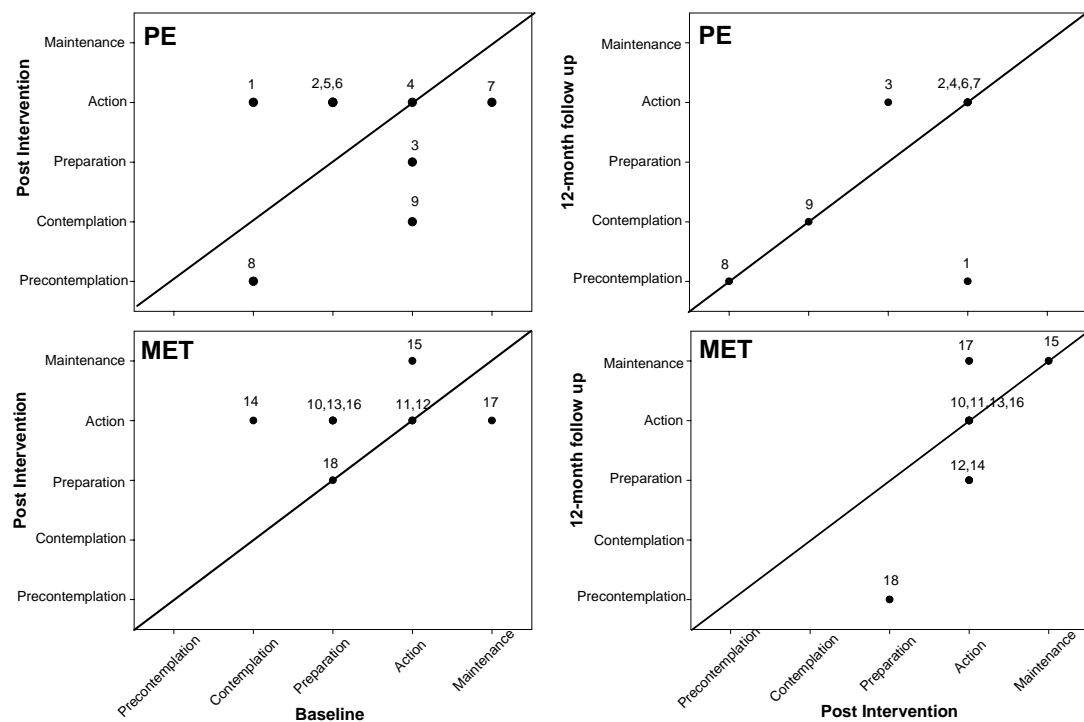


Figure 15. SOCRATES: Stages of change

Treatment Credibility

On the TEI, both interventions were rated highly overall by the participants, with mean credibility ratings of 83% and 89% for PE and MET respectively, suggesting that both interventions were considered to have high credibility (Table 18). On no items was MET rated less than a four out of seven, whereas PE was rated less than a four on three items (items 5, 6 and 10), relating to how much the procedures were liked, the likely effectiveness of the treatment and the participants' general reaction to the treatment. While total TEI scores were not statistically equivalent for PE and MET, they were also not statistically different, resulting in statistical indeterminacy (Table 19).

Table 18. TEI: summary of results

Item	Mean		Range	
	PE	MET	PE	MET
1	5.667	6.444	4–7	4–7
2	5.447	6.444	4–7	4–7
3	6.222	6.111	4–7	4–7
4	6.333	6.111	4–7	4–7
5	4.778	6.111	3–7	4–7
6	5.222	5.778	3–7	4–7
7	5.0	6.333	4–7	5–7
8	6.111	6.889	4–7	4–7
9	6.889	6.333	6–7	4–7
10	5.556	6.556	1–7	5–7
Total	83%	89%	66-100%	74-100%

Table 19. TEI: inferential confidence intervals and results of statistical tests – TEI total score

	95% CI	Different	Equivalent ($\Delta=8.963$)
PE	52.129–64.760		
MET	58.609–65.613	ns	Ns

$\Delta=1$ standard deviation of PE and MET samples

ns=not statistically significant at .05 level

Treatment Integrity

Ninety four percent of the audiotapes reviewed by the independent rater, blind to condition, were accurately identified as either PE or MET sessions. All MET sessions were correctly identified as MET and one PE was incorrectly identified as MET. This suggests that these were distinct interventions.

Cost: Resource Utilisation

MET and PE were statistically different both in the number of appointments taken for the intervention and in the duration of these appointments, with MET taking more appointments and of longer duration than PE (Table 20). They were equivalent, however, in terms of the number of additional appointments attended over the course of the study. Yet, PE participants tended to miss more appointments than MET participants, although the difference was not large enough to be statistically significant.

Table 20. Resource utilisation inferential confidence intervals and results of statistical tests – PE and MET

Appointments	Mean	95% CI	Different	Equivalent
<i>Total attended</i>				$\Delta=0.7$
PE	2.667	2.123–3.21	*	ns
MET	4.000	4.000		
<i>Duration (mins)</i>				$\Delta=8.8$
PE	22.909	20.102–25.716	*	ns
MET	40.528	38.434–42.620		
<i>Extra</i>				$\Delta=2.4$
PE	2.444	1.081–3.808	ns	*
MET	2.444	1.495–3.695		
<i>Missed</i>				$\Delta=1.7$
PE	1.222	0.453–1.991	ns	ns
MET	1.111	0.028–1.202		

$\Delta=1$ standard deviation of PE and MET samples

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Results – Part B

Part B comprises the results of the three participants who received PE, but then, once the follow-up period was completed for PE, agreed to extend their participation in the study to include receiving MET from the same DNE from whom they have previously received PE.

Diabetes Outcome

There was no clinically significant change in HbA1c results for all three participants post-PE (Figure 16). There was, however, a clinically significant decrease in HbA1c post-MET for one participant (Case 4) which was followed by further clinically significant decreases over the course of follow-up, such that at 6-month follow-up her HbA1c was near the 7% target. Similarly, there was no clinically significant change in all three participants lipid profiles post-PE (although Case 9's lipid profile improved over the course of follow-up), but post-MET there again was an improvement in Case 4's lipid results (Figure 17-19).

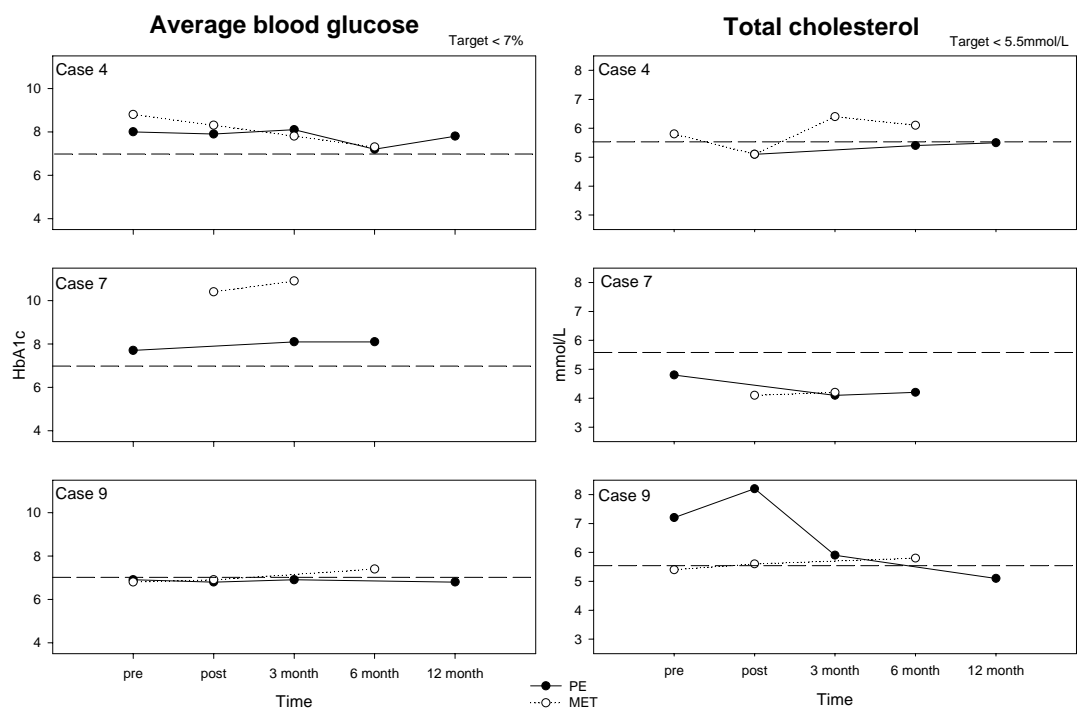


Figure 17. Average blood glucose and total cholesterol

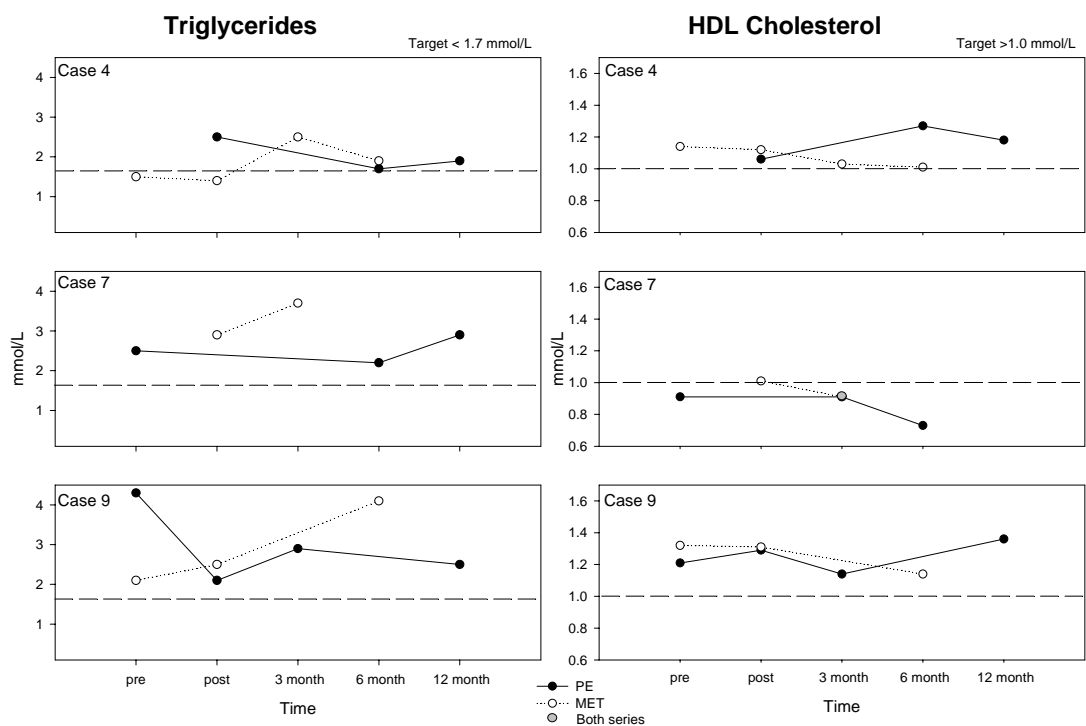


Figure 18. Triglycerides and HDL cholesterol

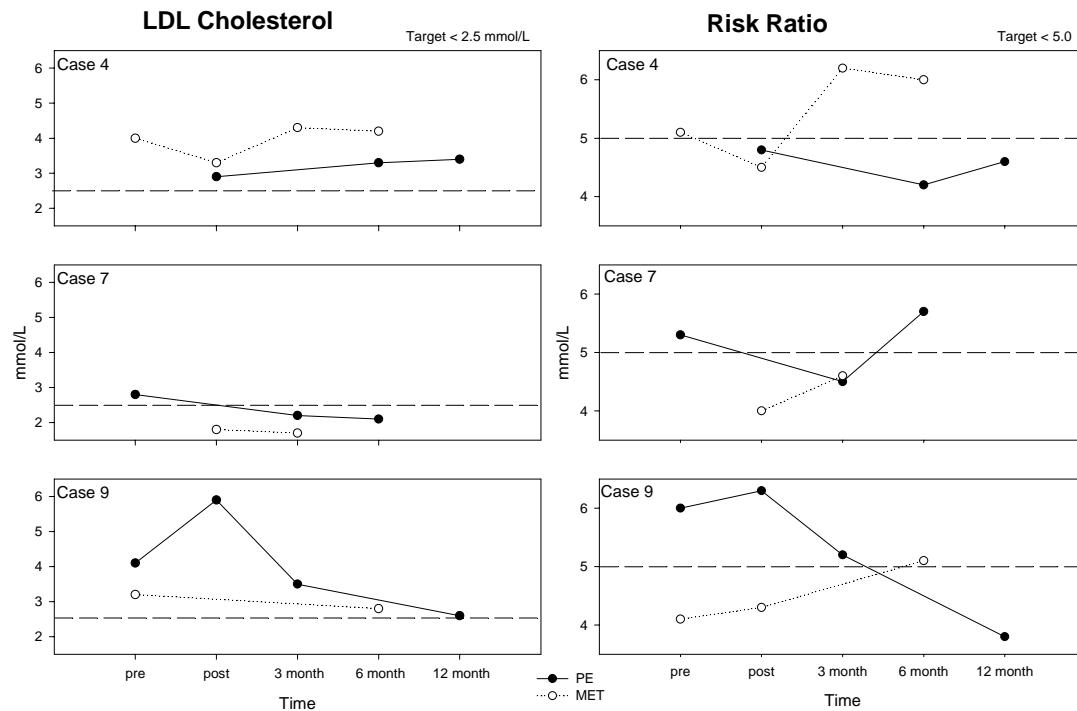


Figure 19. LDL cholesterol and risk ratio

Self-monitored blood glucose data

During PE there appears to have been an improvement in self-monitored blood glucose level for Case 4 from baseline in the latter part of PE, with self-monitored glucose levels falling within the target range (Figure 20). While the 2-week follow-up data shows a trend back to the higher levels obtained during baseline, the data (although limited) suggest that the improvement in self-monitored blood glucose level may have been maintained throughout follow-up. Yet, there appears to have been a return to pre-PE baseline levels by the time baseline for MET was initiated (Figure 20). During MET self-monitored glucose results were quite variable, with some falling within the target, but the majority above this level. At 2-week follow-up the self-monitored glucose level appears similar to baseline, but there appears to have been downward shifts in the self-monitored glucose level at both 3- and 6-month follow-up.

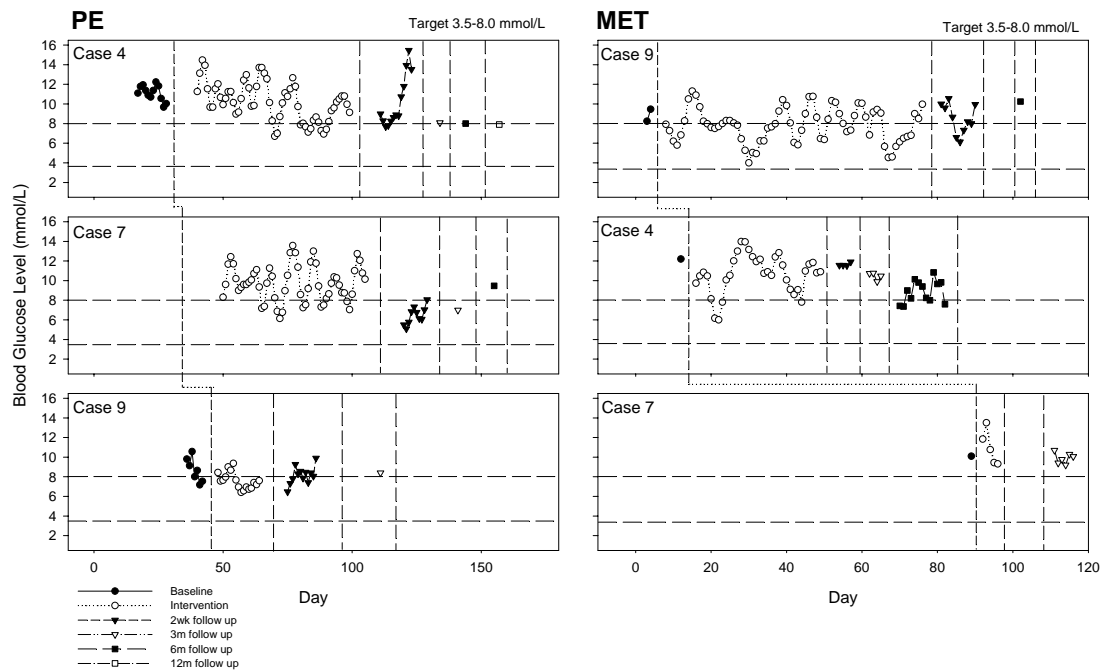


Figure 20. Results from SMOBG

Unfortunately, Case 7 did not engage in SMOBG during baseline for PE, so comparisons with PE and pre-intervention levels are not possible (Figure 20). During PE there does not appear to be any change in the blood glucose level. There, however, appears to have been an improvement at 2-week and 3-month follow-up, with most of the results in the target range, but this does not appear to have been maintained at 6-month follow-up. Although data from SMOBG are limited for MET, there does not appear to have been a change in the level of self-monitored blood glucose during MET or at 3-month follow-up.

Data from SMOBG for Case 9 suggest a decrease in self-monitored blood glucose level towards the end of PE, falling within the target range at the end of PE (Figure 20), although the data was already trending downwards at baseline. There appears to be a trend towards baseline level during 2-week follow-up, which was maintained at 3-month follow-up. Unfortunately, SMOBG did not occur at 6- and 12-

month follow-up. Data from SMOBG for MET, however, suggest an increase in self-monitored blood glucose level at baseline, but a downward trend during MET, with at least 50% of SMOBG data in the target range during MET (Figure 20). While this improvement appears to have been maintained during 2-week follow-up, there appears to have been a return to baseline level at 3-month follow-up.

Intermediate process variables

Self-management behaviour

All three participants chose dietary (compliance or regular eating) or weight loss as target behaviours for change during PE, whereas during MET, all three chose increased SMOBG as one of their goals for change. The data suggest that, whereas all three participants were unsuccessful in changing their target behaviour during PE (Figure 21-23), they all increased the frequency of SMOBG during MET, although the increase was not maintained during follow-up for at least one participant (Case 9).

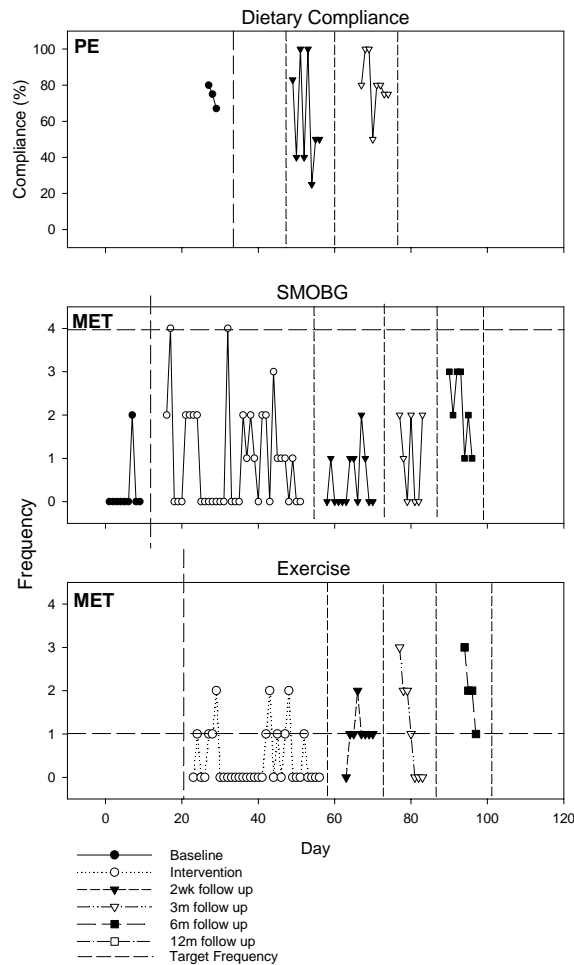


Figure 21. Self-management goals - Case 4

Case 4. Her goal during PE was to improve dietary compliance. It is unclear, however, whether she achieved the goal of improved dietary compliance during PE as she ceased monitoring her food intake during PE. Self-monitoring at 2-week follow-up suggested deteriorating dietary compliance, but an improvement in dietary compliance at 3-month follow-up (Figure 21).

During MET she had two goals (i.e., to increase the frequency of SMOBG to four times per day, three days per week, and engage in daily exercise). The frequency of SMOBG increased from a baseline of no testing (with the exception of one day in which two tests occurred) to 50% of days in which testing occurred between 1-4 times during MET, including two days during MET in which she tested four times per day

(Figure 24). Furthermore, the increase in SMOBG appears to have been maintained at 2-week and 3-month follow-up, with testing (1-2 tests per day) occurring on approximately 50% of days, and there appears to have been further improvement at 6-month follow-up with testing (1-4 tests) occurring on every day.

Unfortunately, baseline data was not collected for the frequency of exercise, so conclusions cannot be drawn regarding her goal of exercising daily (Figure 21). Yet, there appears to be a trend towards daily exercise during follow-up, with exercise occurring on all but one day at 2-week follow-up, four days out of seven at 3-month follow-up and daily 6-month follow-up.

Case 7. He had two goals during PE – to eat more healthily and more regularly (i.e., six times per day). Firstly, in terms of eating more healthily, there does not appear have been an improvement in dietary compliance during PE (Figure 22), with considerable variability (range 0-100% compliance). There, however, appears to have been an improvement in dietary compliance during 2-week follow-up, which was maintained throughout follow-up, although there was still considerable variability (range 0-100%) in compliance. Additionally, he does not appear to have achieved his second goal of eating more regularly, with the number of meals/snacks consumed during PE and at follow-up similar to baseline. Self-monitoring at 6-month follow-up, however, indicated he was eating four times per day (Figure 22).

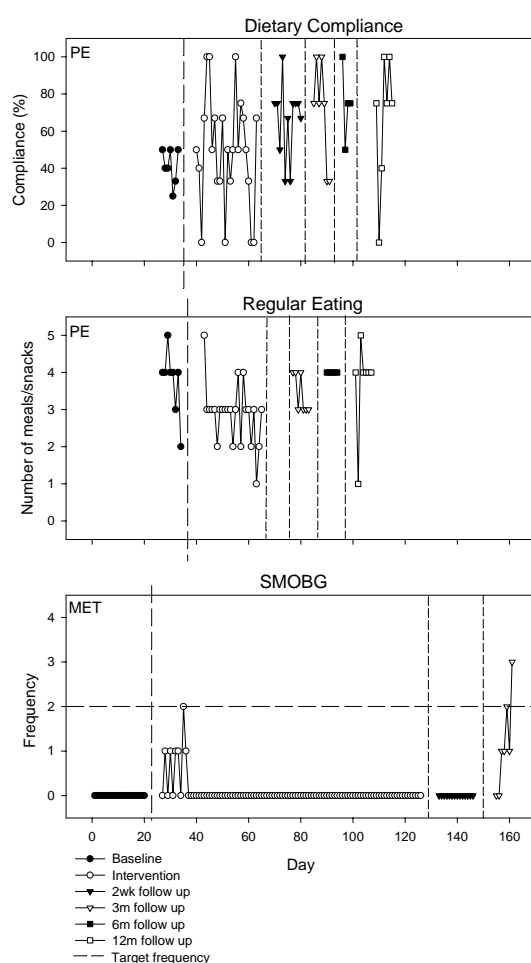


Figure 22. Self-management goals – Case 7

His goals during MET were to take his medication as directed and to increase SMOBG to two times every second day. Unfortunately, he did not record data on his medication use, so his achievement of this goal cannot be assessed, although notes on the clinical file indicate that during MET he reported that he was taking his medication whereas previously he had not. Additionally, there appears to have been an increase in SMOBG, from no testing pre-MET to testing at least once every second day (with one day in which testing occurred twice) in the initial stages of MET (Figure 22). This increase, however, was not maintained beyond the first two weeks of MET, with a return to no testing for the remainder of MET and two-weeks post-MET. Yet, there was again an increase in SMOBG at 3-month follow-up with testing (1-3 times) occurring five days out of seven. Unfortunately, he lost his meter before

the 6-month data could be downloaded, so it is uncertain what was happening with regards to SMOBG at this point.

Case 9. She had two goals during PE – to eat more healthily and lose weight. She, however, did not self-monitor her food intake. Consequently, conclusions cannot be drawn regarding dietary compliance. She did not achieve her second goal of losing weight, with her weight increasing from baseline to post-PE and over the follow-up period (Figure 23).

Case 9 had two goals during MET – again, to eat healthily, and to increase the frequency of SMOBG to four times a day, three days per week. Once again she did not record her food intake and so conclusions cannot be drawn regarding dietary compliance. There, however, appears to have been an increase in SMOBG from no testing at baseline (with the exception of one day in which she tested four times) to testing on approximately 50% of days for most of MET, and she achieved her goal of testing four times per day, three days per week in the first week of MET (Figure 23). The frequency of testing, however, declined back to baseline level by the end of MET. She was testing more frequently 2-weeks post-MET, but at 3- and 6-month follow-up the frequency of SMOBG had decreased to baseline level.

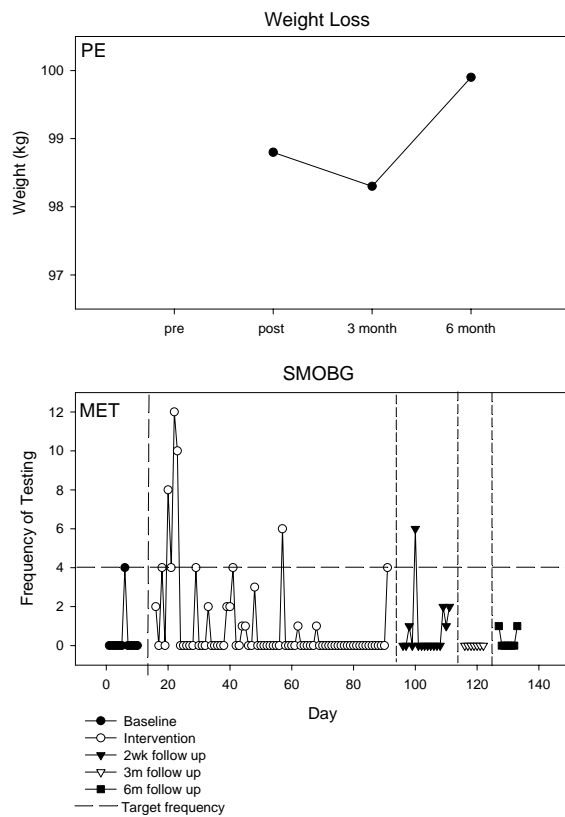


Figure 23. Self-management goals – Case 9

Psychosocial measures

PMDI results suggest that two (Case 4 and 9) of the participants considered PE was equally effective as the TAU they received at baseline, whereas Case 7 considered PE to be more effective than TAU (Table 21). Similarly, two participants (Case 4 and 7) considered MET to be as effective as the TAU they received at baseline, whereas Case 9 considered MET to be more effective than TAU at baseline.

Table 21. Clinically significant change (RC) on the PMDI, PAID, DKT and TEI – Cases 4, 7 and 9 for PE and MET

	PMDI				PAID		DKT	TEI
	<i>Treatment Effectiveness</i>		<i>Seriousness</i>					
	Post	Follow-up	Post	Follow-up	Post	Follow-up	Post	
Case 4								
PE		-4.39		+2.52				
MET		+2.93		-2.82			+3.84	+2.68
Case 7								
PE	+5.12	+3.58			-2.22			
MET				-5.54				+2.34
Case 9								
PE			+3.02	-2.01	+2.82	-3.22		
MET	+2.24	-4.03		+2.01	+2.01	-2.82	-3.84	

+ =clinically significant increase in score (i.e., RC>1.96) from baseline

- =clinically significant decrease in score (i.e., RC>1.96) from baseline

NB: empty cell means there was no clinically significant change in the score from baseline

There was no change in the participants concern about the seriousness of their diabetes after both interventions, apart from Case 9 whose score on the PMDI indicated an increase in concern post-PE (Table 21). Mixed results were obtained for diabetes seriousness at follow-up for PE, whereas two (Case 4 and 7) of the participants were less concerned about the seriousness of diabetes at follow-up.

There was also no clinically significant change in the participants' knowledge about diabetes post-PE as indicated by their scores on the DKT (Table 21). Post-MET the results, however, were mixed. Mixed results were also obtained for the three participants on the PAID post-PE, whereas two of participants scores remained unchanged post-MET, suggesting no change in emotional adjustment to diabetes post-MET (Table 21).

Two (Case 7 and 9) of the three participants scores on the SOCRATES suggested a decrease in motivation to change following PE, whereas motivation to change remained unchanged or increased (Case 9) following MET (Figure 24).

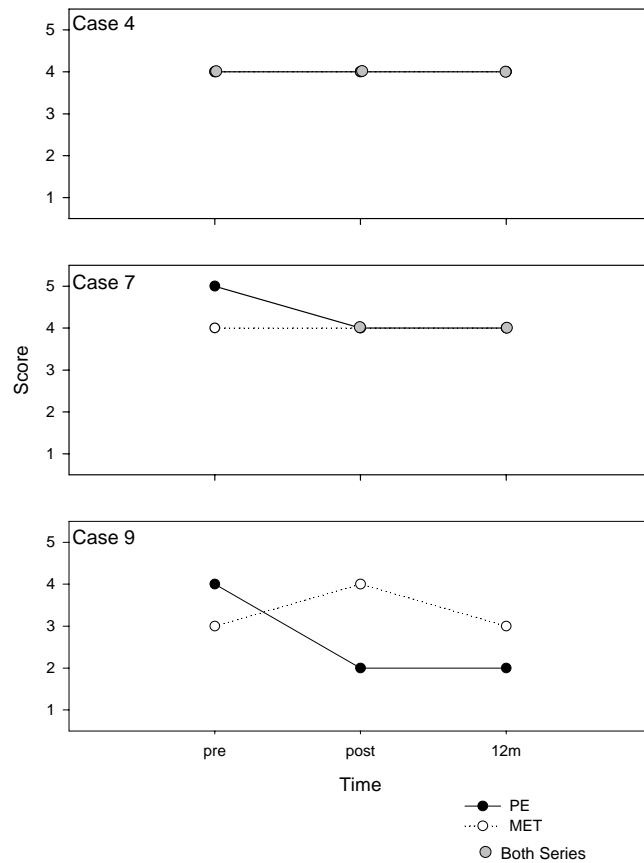


Figure 24. Stages of change (SOCRATES)

Treatment credibility

Both interventions were rated highly on the TEI by all three participants, suggesting that both were considered highly credible interventions, with mean credibility ratings of 58% and 63% for PE and MET respectively. MET, however, was given a clinically significant higher rating than PE for two (Case 4 and 7) of the participants.

Cost: Resource utilisation

As in Part A, MET comprised more appointments than PE. Participants also attended more additional appointments during the MET phase than during the PE phase. Participants, however, missed fewer appointments during the MET phase (Table 22).

Table 22. Resource utilisation during the course of the study – PE and MET

Appointment	PE	MET
Total attended	2.667	4.000
Extra	1.667	2.333
Missed	1.667	0.667

Summary

The findings of this within-subject comparison of PE and MET, consistent with Part A findings, suggest that MET led to improved diabetes self-management, whereas the evidence did not support PE as a means of improving diabetes self-management. When the participants received PE, they either did not record data relevant to the treatment goal (e.g., dietary compliance) or, when data was available, there did not appear to be any improvement in diabetes self-management, with the exception of Case 7 who showed some improvement in dietary compliance at 2-week follow-up which was maintained throughout follow-up. In contrast, each participant when he/she received MET appears to have made some progress towards at least one diabetes self-management goal, which for all participants was increased SMOBG.

Furthermore, for one of the participants (Case 4) there was evidence that the changes in diabetes self-management behaviour achieved with MET may have led to improved metabolic control, with clinically significant decreases in HbA1c over the course of the MET phase such that her blood glucose at 6-months post-MET was near the 7% target. Participants' lipid profiles did not appear to be improved with either intervention, although one participant (Case 9) had a marked improvement in her lipid profile 3-, 6- and 12-months post-PE, which cannot be entirely attributed to medication as her medication for dyslipidaemia had been stopped 12-months post-PE.

The results on the psychosocial measures were also similar to those in Part A. Both interventions tended to be considered as effective as TAU at baseline, and did not appear to have altered the participants' concern about the seriousness of their diabetes, future complications, and the effect on their life immediately post-intervention. There, however, was a decrease in concern for two of the three participants at 6-month follow-up after MET. There was no evidence that PE or MET increased the participants' knowledge about diabetes, and no evidence that either intervention affected the participants' emotional adjustment to diabetes. There did, however, appear to have been a deleterious effect on participants' (n=2) motivation to change following PE, whereas their motivation tended to remain unchanged (n=2) or improved following MET. Lastly, both interventions were rated highly in terms of treatment credibility. The participants, however, tended to rate MET higher than PE.

Discussion

Group data suggest that both interventions may have contributed to clinically significant improvements in glycaemic control. The mean decrease in HbA1c for both interventions over the course of the study was .70% and .67% for PE and MET respectively. This is higher than the mean reduction of .43% reported in recent meta-analyses of educational and behavioural interventions for Type 2 diabetes (Gary et al., 2003) and of MI applied to disease (Rubak et al., 2005).

The decreases in HbA1c in the current study, however, were not to the level of statistical difference, apart from one exception (i.e., MET at 6-month follow-up). This lack of statistical significance may be due to a lack of power because of the small number of participants in each group. Despite the lack of power, there was a statistically significant improvement in glycaemic control from baseline to 6-months after MET. This suggests that the effect of MET on glycaemic control continued up to 6-months post-intervention.

Yet in the current study, HbA1c results for both groups at 12-month follow-up were statistically equivalent to baseline, suggesting that the decreases were not maintained at 12-month follow-up. This result in itself, however, is still clinically significant as it contrasts with the natural history of diabetes, which is for blood glucose to rise over time (Yudkin, 2005).

A recent meta-analysis of research on self-management education for Type 2 diabetes found that the mean decrease in HbA1c was .76% post-intervention but fell to only .26% with follow-up of 4-months or greater (Norris et al., 2002). The findings of the current study that effect for PE decreased over time, from .95% post-PE to .02% at 12-month follow-up, is consistent with this meta-analysis, although the effect on HbA1c in the current study appears to have not been lost until after 6-months.

The mean decrease in HbA1c of .67% for the current study compares favourably with the results of recent meta-analyses of psychological interventions for Type 2 (Ismail et al., 2004) and Type 1 (Winkley et al., 2006) diabetes. Winkley et al (2006), for example, found only a mean decreased of .22% in HbA1c after psychological intervention for adults with Type 1 diabetes. While the mean decrease of .67% in the current study is less than the .76% reported by Ismail et al (2004) for psychological interventions with Type 2 diabetes, the psychological interventions in the meta-analysis were considerably longer (i.e., mean of 11 sessions, range from 5-50 sessions) than the MET provided in the current study (i.e., four sessions). Additionally, most (i.e., 86%) of the psychological interventions in the meta-analysis used specialists (typically psychologists) to provide the intervention, whereas in the current MET was provided study by DNEs. Thus, it could be argued that MET is more cost-effective, and certainly is more amenable to wider scale application than intensive, specialist-provided psychological interventions.

While the group data did not show a decrease in HbA1c (a measure of the average blood glucose over the previous 8-10 weeks) 2-weeks post-MET, this was may have been a function of the relatively short time (10 weeks) from baseline to

post-test in most cases. Nevertheless, the decrease in HbA1c in the current study of 1.25% 6-months post-MET is comparable with the mean decrease in HbA1c of 1.2% reported in the three other studies (Smith et al., 1997; Viner et al., 2003; Channon et al., 2007) which found statistically significant decreases in HbA1c following MI with patients with diabetes. It should also be noted that these other studies tended to comprise longer MI (i.e., mean of 4.7 sessions, but up to 16 sessions, for up to 6-months), which was conducted by specialist interventionists rather than usual clinical staff, as in the current study. Moreover, in contrast to the current study, the two studies that evaluated the effectiveness of MI provided by usual clinical staff (Clark et al., 2004; Rubak, 2005) found there was no statistically significant decrease in HbA1c following MI.

Consistent with the group data finding of a statistically significant decrease in HbA1c at 6-months follow-up, the individual data suggests clinically significant decreases (i.e., 0.5%) in HbA1c for four of the MET participants post-intervention, which extended to five MET participants at 6-month follow-up. The data from the self-monitored blood glucose levels, however, were less clear. This in part was due to the data itself being highly variable and therefore difficult to analyse, but may also have been a function of the nature of the participants testing which contributed to this data being a less reliable measure of overall blood glucose. For example, rather than testing their blood glucose at regular times, some participants reported testing when they thought their level was likely to be low, as this made them feel less anxious and would please their health practitioner(s), while others reported times when they tested (and sometimes repeatedly) because they were anxious that their blood glucose may have been high.

The failure of the improvements in glycaemic control to be maintained at 12-month follow-up, raises the possibility that some form of booster session(s) may be necessary 6-12 months after MET, and perhaps regularly thereafter. Therefore, it is recommended that future research investigates whether the addition of booster sessions to MET contributes to further, or maintenance of, improvements in glycaemic control.

Group data also suggest that both interventions may have contributed to statistically significant improvements in the participants' lipid results. There was a statistically significant decrease in the PE participants' triglyceride results from baseline to post-PE and at 12-month follow-up, whereas there was a statistically significant decrease in the MET participants' total cholesterol and LDL cholesterol at 12-month follow-up. This finding for MET is similar to that reported for MI on total cholesterol and LDL cholesterol in relation to cardiovascular disease (Kreman et al., 2006), although the statistically significant decrease occurred 3-months after MI, whereas the statistically significant decreases in the current study were not achieved until 12-month follow-up.

The multiple-baseline data suggest the mechanism by which the improvements in metabolic control may have been achieved. MET appears to have led to somewhat improved diabetes self-management, particularly increased SMOBG, in most cases. In contrast, the mixed results observed did not support PE as a means of improving diabetes self-management. Thus, it is likely that the improvement in self-management behaviour (e.g., SMOBG) with MET contributed to the clinically significant improvements in diabetes outcome (HbA1c and lipids).

There appears to have been a differential effect on readiness for change (as measured by the SOCRATES) with the two interventions. That is, while the MET participants' motivation (with one exception) either increased or remained unchanged, PE appears to have led to an equal number ($n=4$) of participants becoming less motivated (i.e., more resistant to change). This finding is consistent with previous research suggesting that advice-giving may lead to resistance (Miller & Rollnick, 1991; Patterson & Forgatch, 1985, Stott & Pill, 1990).

It could be expected that advice-giving, in particular to individuals who are not ready to change their behaviour (i.e., in the pre-contemplation or contemplation stage of change), may have a negative effect on motivation as these individuals have not made a decision to change. The results of the current study, however, suggest that there was no particular stage of change which was more vulnerable to the deleterious effects of advice-giving on motivation, with participants who became more resistant to change being assessed at baseline to be in a range of stages of change (i.e., contemplation through to maintenance). In contrast, participants who were in the preparation stage of change at baseline, tended to show increased motivation after either intervention. This suggests that, having decided to change, PE participants were more receptive to advice.

Further research as to whether there is a stage of change when advice-giving (PE) may or may not be beneficial is recommended. This may then enable health practitioners to be more targeted as to whom they give advice to, and when advice is provided. PE might then be given to individuals who are most receptive to advice and therefore more likely to benefit from it. Those individuals who are less likely to

benefit from advice would be given some other form of intervention, such as MET, which focuses on the individual's motivation to change.

Of concern is that one participant receiving MET became less motivated to change. Further analysis suggests that the quality of MET provided to this participant was not below the standard received by the other participants. It is most likely, then, that extraneous factors (such as other life events) may have influenced the change in motivation.

The above results regarding motivation to change should be treated with some caution, however. A limitation of the SOCRATES is that it measures motivation to change diabetes self-management generally, rather than motivation to change specific self-management behaviours. The SOCRATES as a global measure would not necessarily pick up changes in motivation to change specific behaviours, even though such behaviour-specific motivational changes may occur.

Additionally, the TTM of change (Prochaska & DiClemente, 1982; Prochaska et al., 1992) upon which the SOCRATES is based has been questioned as to whether it is a “valid description and explanation of the process of change” (Sutton, 2001, p.175), and the SOCRATES has been criticised for failing to distinguish between different stages in the TTM. While the SOCRATES, “does not appear to measure the stage of change constructs as conceived by Prochaska and DiClemente ..., the scales of the SOCRATES seem better understood as continuously distributed motivational processes that may underlie stages of change” (Miller & Tonigan, 1996, p.84).

Individual case data suggest that PE had little effect on the PE participants' knowledge about diabetes as measured by the DKT, with no clinically significant changes in the scores obtained for all but one participant. Yet, despite the provision of information not being a focus of MET, three MET participants had clinically significant increases in diabetes knowledge post-MET, and four at 12-month follow-up. This suggests that for some individuals MET may have contributed to increased knowledge. Increased knowledge, however does not necessarily translate to behaviour change or improved diabetes control (Rubin et al., 1991; Bahru & Abdulkadir, 1993).

Participants in both interventions were fairly evenly distributed between those experiencing low to moderate levels of diabetes-related distress and those experiencing high levels of distress at baseline as measured by the PAID. Statistical analysis of the group data did not reveal a statistical difference between PE and MET participants' PAID results at baseline, post-intervention or at 12-month follow-up, although the results were statistically indeterminate at baseline, with higher levels of distress for the PE participants. Group data, however, suggest that there may have been improvement in the participants' emotional adjustment to their diabetes over the longer term, with a statistically significant difference between baseline and 12-month follow-up results for both interventions. For PE, however, this may simply be the effect of the individual with poor emotional adjustment (near the diabetes burn-out range) being lost to 12-month follow-up. Additionally, although statistical analysis of MET group data found a statistical difference, the results were also statistically equivalent and therefore statistically indeterminate. Again, this failure to find

statistical significance (at baseline and 12-month follow-up) may be a function of a lack of power.

Group data, however, suggests no statistically significant change in PE and MET participants' emotional adjustment post-intervention, which is supported by the individual case data which suggest no clinically significant change in individual participants' emotional adjustment to diabetes pre- and post-intervention. Nevertheless, the changes in the participants PAID scores for both interventions from baseline to post-intervention (PE $d=.30$, MET $d=.47$) and to 12-months follow-up (PE $d=.62$, MET $d=.65$) were similar to the small ($d=.32$) to moderate ($d=.65$) effect sizes reported for the PAID following a range of interventions (educational and psychological) for diabetes (Welch et al., 2003).

The mean composite scores on the PMDI at baseline for the PE and MET participants were similar to those reported by Clark et al. (2001), with patients with Type 2 diabetes (i.e., seriousness=2.70, effectiveness=3.80). The scores indicated that the participants perceived their diabetes as only slightly serious and that they were only slightly worried about its threat to their future (PE=2.08, MET=2.99), but that their beliefs about the effectiveness of treatment for diabetes were somewhat stronger (PE=3.01, MET=3.60).

The MET participants were more concerned at baseline about the current seriousness of their diabetes, future complications, and the effect on their lives than the PE participants. This may reflect the MET participants' poorer glycaemic control at baseline (i.e. their HbA1c tended to be higher than the PE participants, although the

difference was not statistically significant), and longer duration of diabetes (i.e. 10-15 years post-diagnosis compared to 3-11 years for the PE participants), and therefore longer exposure to the effects of hyperglycaemia contributing to more diabetes-related complications. That is, while a similar number (about half) of PE and MET participants had experienced complications from diabetes, the MET participants had experienced more diabetes-related complications (on average two per participant with complications) than the PE participants (only one complication per participant with complications).

Post-MET individual data indicate that four MET participants experienced a decrease in concern about diabetes, with group data indicating a statistically significant decrease in their concern such that they were no longer statistically different, although still not statistically equivalent, to the PE group. This decrease in concern, however, appeared to wane at 12-month follow-up.

The MET participants may have had lowered concern about the seriousness of their diabetes, future complications, and the effect on their lives post-intervention because they had successfully made changes in their diabetes self-management, which they considered likely to be permanent. Therefore, they may have believed that they had reduced the risk of future diabetes-related complications, thereby altering their beliefs about the seriousness of their diabetes. On the other hand, their beliefs about the seriousness of their diabetes may have increased at 12-months when the improvements in glycaemic control achieved at 6-month follow-up were not being maintained.

Previous research suggests that a higher level of concern about the seriousness of diabetes is likely to contribute to greater engagement in diabetes self-management behaviour (Hampson et al., 1990; Hampson et al., 1995; Skinner & Hampson, 2001). The baseline PMDI results in the current study appear to support these findings. The MET participants were more concerned about the seriousness of their diabetes, and subsequently were more successful in achieving their diabetes self-management goals, including increased SMOBG. It may therefore be that the better outcome for the MET participants was due to their beliefs about the seriousness of their diabetes, rather than a function of having received MET. Future research would need to explore this, using groups of participants who were matched for beliefs about diabetes' seriousness at baseline.

The fact that the participants were referred for further assistance with diabetes management, however, suggests that the participants were maintaining inadequate diabetes self-management despite their concerns about the seriousness of their diabetes. Therefore it is likely that MET contributed to the improvements in diabetes self-management during the study, rather than their concerns about their diabetes. The subsequent improvements in their diabetes self-management behaviour, coupled with the improvements in blood glucose, may then have led to the decrease in concern about the seriousness of diabetes after MET.

Considering Hampson et al's (1995) results showing a relationship between beliefs about treatment effectiveness and diabetes self-management behaviour, it might have been expected that the MET participants would have considered MET more effective than TAU, given that they made changes in their diabetes self-

management during MET. Individual and group data, however, suggest no clinical or statistical difference between the PE and MET participants' perceptions of the effectiveness of TAU and PE or MET, and both interventions were rated highly in terms of credibility (TEI).

Limitations of the Study

The number of participants in the study is small (n=9 in each intervention group, with n=2 staff providing the interventions), however, limiting the strength of the conclusions that can be drawn from the current study. Additionally, the variability in the goals for change selected by the participants also limited the number of replications. The conclusions that can be drawn from the current study, especially regarding the generalisability of the results, should therefore be treated with caution.

Part B, however, provides a replication of the results in Part A, and therefore further support for the conclusions, with similar findings (especially regarding MET leading to improvements in SMOBG). A limitation in Part B, however, is that it is unclear why these three participants took up the offer of further intervention and the other six did not. For example, it could be that the participants in Part B were more motivated or compliant, and hence the reason for their agreeing to participate in a second study. Yet, examination of the demographic, questionnaire and blood glucose data suggests that these three participants were more similar than different to the other six PE participants at baseline for both PE and MET. At baseline for PE the three participants who agreed to partake in Part B, however, tended to have lower knowledge about diabetes, lower HbA1c, and appeared to be more ready to change

than the other PE participants. This, however, did not appear to contribute to improved outcome with PE, with all three failing to make improvements in their diabetes self-management or improved blood glucose with PE. Interestingly, at baseline for MET the three participants appear to have been more satisfied with the treatment they were receiving at that point and were experiencing less emotional distress related to diabetes when compared to the PE participants at baseline, yet they agreed to participate in Part B.

As it happened, when the same participants received PE and MET provided by the same DNE, results similar to Part A were obtained. Through replicating the results the probability that something other than MET caused the change is reduced (Cooper, Heron & Heward, 1987). Thus, further support is provided for the findings that MET may be an effective intervention for enhancing diabetes self-management and diabetes outcome.

The small sample size in the current study also meant that there was a lack of power for both the statistical tests and effect size calculations, inflating the risk of type 2 error. Despite, the small sample size, however, statistically significant differences and moderate to large effect sizes were found. Conversely, the large number of pair-wise comparisons of means (especially for the lipid results) to test hypotheses may have inflated the risk of type 1 error in the current study. The use of Tryon's (2001) inferential confidence interval approach in the current study to test for statistical difference, equivalence, and indeterminacy that is algebraically equivalent to standard null hypothesis statistical testing (NHST), however, decreases the risk of type 1 as well as type 2 error. For example, Tryon's approach requires that in order

for statistical difference to be claimed, it has to be established that the data is statistically not equivalent as well as statistically different, thereby reducing the risk of type 1 error. Tryon also points out that it is common practice to interpret “marginally” (near the .05 level for example) significant results as trends, and then discuss them as differences, whereas the inferential confidence interval approach provides access to a third alternative; namely that the results are statistically indeterminate. Thus, while ‘this alternative has always been technically available’ (p.373), ‘standard NHST procedures emphasise accepting or rejecting the null hypothesis’ (p.373), whereas the methods proposed by Tryon (2001) ‘clearly incorporate statistically indeterminacy and should make this alternative more salient’ (p.373). Tryon’s (2001) approach also addresses a ‘misuse of NHST procedures’ (p.373) related to reporting of *p* values in which ‘to correctly conduct NHST and properly establish grounds for falsification, one must specify the type 1 alpha level (e.g., .05 or .01) in advance of conducting analysis’ (p.373), whereas ‘this classic NHST step is rarely, if ever taken’ (p.373). Instead, ‘investigators typically select the *p* value after computing the test statistic and then report the highest significance level’ (p.373). Tryon’s procedure avoids this error by ‘requiring the user to establish a level of statistical significance as a necessary condition for calculating test statistics and then report results as significant or not’ (p.373).

Another limitation of the current study related to data analysis, was the reliance on visual analysis for the data related to diabetes self-management behaviour (e.g., frequency of SMOBG, dietary compliance, exercise). Behaviour analysts have suggested that visual analysis of single-case data is generally reliable and conservative (Baer, 1977; Micheal, 1984; Parsonson & Baer, 1978; 1986), arguing

that visual inspection will reveal any intervention effects large enough to be important to clinicians, and that visual analysis yields low error rates (Huitema, 1986) and is conservative in identifying treatment effects (Baer, 1977), however the results of empirical studies (Franklin, Gorman, Beasley & Alison, 1996) suggest that this may not always be true. The results of the current study should therefore be treated with caution as visual analysis was the sole means of interpreting the self-management data.

A further limitation in the current study was that the participants were not randomly assigned to condition, instead nine consecutive referrals received PE and then after the Nurse Educators had received training in MI, nine consecutive referrals received MET. Thus, while there was a lack of random assignment, the intervention condition each participant received was not selected by the researcher.

There was also a lack of control regarding phase change criteria which again arose as a consequence of conducting research within a natural clinical environment. For clinical reasons, baseline was set at a minimum of one week, with the move to intervention dependent on the availability of both the participant and DNE in terms of scheduling intervention appointments. The move from intervention for the PE participants was determined jointly between the participant and the DNE, whereas the move from intervention for the MET participants was determined by time (i.e., the completion of four MET sessions, preferably conducted over six weeks). This, therefore, limited the integrity of the design and interpretations which can be made.

Additionally, in some cases baseline data was limited (or non-existent), and it was not possible for clinical and ethical reasons (i.e., the participants were individuals who had been identified as already struggling with diabetes self-management and to have blood glucose levels which were of concern) to wait for stable baselines before the intervention was introduced as might be expected in single-case design. This, therefore, further limited the conclusions that could be drawn. Furthermore, the blood glucose levels obtained from the memory meters were highly variable which also made interpretation difficult. This high variability within the data, while making interpretation difficult, reflected the reality of the clinical situation with considerable variability in data from self-monitoring of blood glucose. At least using single-case methodology this variability was made evident rather than obscured. HbA1c, however, was used as the primary means of measuring blood glucose data in the current study and is a well accepted measure of diabetes outcome. Additionally, coefficients of variation (Fraser, 2001) were used in calculating delta (the maximum difference that is unimportant or can be dismissed on substantive grounds), to account for known biological variation in the blood glucose and lipid data.

Conclusions

Thus, the conclusions that can be drawn from the current study are highly tentative, however the conclusions that can be drawn, particularly regarding the generality of the results, are strengthened by the fact that it was a clinically-based study. Thus, the external validity of the current study was strong because participants were recruited directly from a real-life clinical setting. Additionally, exclusionary criteria were minimal (i.e., participants aged 16-69 years, and diabetes diagnosed for

at least 12 months). Therefore, the participants (males and females, aged 21-68 years) in the current study are likely to be typical of persons who are experiencing difficulty with diabetes self-management, having been referred (typically by their GP) to the hospital-based secondary treatment centre because there were problems with diabetes self-management. Specifically, their diabetes (Type 1 or Type 2) had been diagnosed for a mean of 10 years (range 1-21 years), and just under half were experiencing diabetes-related complications, ranging from recurrent vaginal thrush through to retinopathy, peripheral neuropathy and nephropathy. Furthermore, the study was conducted in a hospital-based clinic setting. Appointment sessions were scheduled within usual clinic time, and clinic staff performed the interventions without extensive training (i.e. only two days training, plus supervision of audio-taped sessions for MET).

In conclusion, while it is not proven, it appears that MET, conducted by usual clinical staff (i.e., DNEs) in a hospital-based clinic, has promise as an effective intervention to improve diabetes outcome (Hypothesis 1), through enhanced diabetes self-management (Hypothesis 2), particularly SMOBG, for individuals with diabetes (particularly Type 2 diabetes), and may have been more effective than the then current standard treatment of PE (Hypothesis 3). There was also evidence that MET was well-received by the participants (Hypothesis 4), and there were no adverse effects from MET (Hypothesis 5), but rather that MET contributed to increased motivation (Hypothesis 6) and a decrease in concern about the seriousness of diabetes and worry about future complications. Contrary to expectations, there was no evidence that PE contributed to improved knowledge about diabetes (Hypothesis 7).

STUDY 2: GENERALISATION

Establishing the generality of single-case research is important if the findings of earlier studies are to be extrapolated to other individuals or to future contexts and circumstances (Barlow et al., 1984; Blampied, 1999). One important aspect of generality within single-case research is concerned with whether an intervention that was successful with one individual will be successful with others (Kazdin, 1978). As successful between-subject replications accumulate, it can be inferred that the intervention has generality over the range of individual variation represented by the participants (Hersen & Barlow, 1976). A second important aspect of generality is the ability of a variety of practitioners/intervention agents to deliver the intervention. This aspect of generality is examined when the effect of MET provided by different health practitioners (e.g., dietitians compared to nurse educators) is studied. This enables exploration of how variation in the type of practitioner impacts on outcome (Blampied, 1999). In so doing systematic replication is being employed (Sidman, 1960).

The aim of Study 2, therefore, was to further evaluate the effectiveness of MET by testing whether the results achieved for MET in Study 1 could be generalised to another professional context, in this case dietetics applied to diabetes. Study 1 investigated MET provided by nurse educators, whose focus tends to be on improving diabetes self-management via behaviours such as SMOBG and medication use. Study 2, in comparison, investigated MET provided by dietitians, whose focus tends to be on diet and exercise as major contributions to diabetes self-management.

In summary, Study 2 tests for the generality of the earlier findings by testing for the effects on outcome of individual variation within participants, and the effects of variation of the health practitioner providing the intervention. Specific hypotheses were that, similar to the results of Study 1, MET would lead to improved diabetes outcome (i.e., lower HbA1c and improved lipid profile) (Hypothesis 1) through improved diabetes self-management (which in Study 2 it was predicted would mostly comprise dietary changes) (Hypothesis 2), and would be more effective than PE (Hypothesis 3). Additional hypotheses were that MET would be considered an acceptable intervention to participants (Hypothesis 4), and there would not be any adverse effects from MET on the participants' adjustment to diabetes (Hypothesis 5), but that (based on the results of Study 1) there would be an improvement in the participants beliefs about the seriousness of diabetes after MET (Hypothesis 6). It was also hypothesised that there would be an increase in motivation to change in MET participants (Hypothesis 7), and (based on the results of Study 1) that neither intervention would contribute to an increase in diabetes knowledge (Hypothesis 8).

Method

Procedure

Participants

Patients (aged 16-69 years) who had been referred to dietitians at the Diabetes Centre (i.e., the same setting as in Study 1) for further assistance with managing their diabetes (Type 1 or Type 2), and who had been diagnosed with diabetes for at least 12 months, were approached regarding participation in the study. Participants were not randomly assigned to intervention. All participants continued to receive TAU from their GP.

Initially, seven consecutive individuals referred to the dietitians were approached regarding participation in the PE phase, all of whom agreed to participate, but one subsequently withdrew (a female Caucasian, aged 48 years, with Type 2 diabetes) agreed to participate, but failed to attend scheduled appointments with the Dietician and so was withdrawn from the study (Table 23). Thus, six participants participated in the PE phase. They all had Type 2 diabetes (Table 23). Three were male and two female, with ages ranged from 38-69 years. One PE participant was Maori, with the rest being Caucasian.

Table 23. Characteristics of participants

		Declined	Withdrew	Completed
Diabetes	PE			
	Type 1	0	0	0
	Type 2	0	1	6
Gender	Male	0	0	3
	Female	0	1	3
Ethnicity	Maori		1	1
	Caucasian		0	5
Age (years)	Mean		48	48.6
	Range			38–69
Diabetes	MET			
	Type 1	0	0	0
	Type 2	0	2	5
Gender	Male	0	1	2
	Female		1	3
Ethnicity	Maori		0	0
	Caucasian		2	5
Age (years)	Mean		34.5	54
	Range		32–37	36–63

Once the intervention in the PE phase had been completed and the dietitians had received training in MET, seven further consecutive individuals referred to the dietitians were approached regarding participation in the MET phase, all of whom agreed to participate, but two subsequently withdrew - one because she had a young child and found it difficult attending appointments, and the other after experiencing a head injury. Thus, there were five participants in the MET phase of the study.

All participants in the MET phase also had Type 2 diabetes, and were Caucasian (Table 23). Two were male and three female, with ages ranging from 36-63 years of age. The participants who withdrew from the MET phase were Caucasian, aged 32 and 37 years of age, one of whom was male and the other female, both with Type 2 diabetes.

Thus, the MET participants tended to be a little older (mean of 54.0 years) than the PE participants (mean of 48.6 years). The MET participants also tended to have a slightly longer duration since diagnosis of their diabetes (Table 24).

Table 24. Duration (years) since diagnosis of diabetes

Participants	Mean (years)
PE	4.6
MET	6.8

For more detailed description (i.e., reason for referral, diabetes complications, other health problems, medication and employment status) of PE and MET participants, and individual case descriptions see Appendix 12.

Staff

Two dietitians agreed to participate in the study, one of whom had practiced dietetics for one year following qualification, and the other for five years.

Intervention

Both interventions were similar to those in Study 1. PE was the standard intervention provided at the Diabetes Centre at the time that this research began, and comprised the provision of information and advice about diabetes and diabetes self-management, specifically diet and exercise. As in Study 1, the duration, number and frequency of sessions were determined, according to usual clinic practice, by the dietitian in consultation with each participant however, PE typically comprised an initial appointment of 60 minutes, followed by 30 minute sessions, on a monthly basis. MET was provided as in Study 1 (i.e., four 30-40 minutes sessions on weeks 1, 2, 4 and 6).

Training

The dietitians received two days (12 hours) training in MET (as previously described in Study 1), and were provided with the manual (Appendix 1) which outlined key MI principles, strategies and techniques, and the process for MET.

Design and Measures

A non-concurrent multiple baseline design (Watson & Workman, 1981) across individuals was used. Outcome measures and analyses were the same as for Study 1. Group comparisons using inferential statistics, however, were not used in Study 2 due to the small (i.e. PE $n=6$, MET $n=5$) sample size, so the focus for interpretation of Study 2 results was on clinically significant change.

Results

As in Study 1, results will now be reported beginning with primary outcome measures (i.e., diabetes outcome, comprising HbA1c and lipids), followed by the intermediate process variables (i.e., diabetes self-management behaviour and psychosocial measures).

Primary Outcome Measures: Diabetes Outcome

Blood glucose

HbA1c. Changes in HbA1c are shown in Figure 24. Four PE (Case 19, 21, 22, and 24) and two MET (Case 25 and 28) participants had clinically significant decreases in HbA1c post-intervention. Mixed results were obtained for the PE participants during follow-up, with two PE participants for whom there was little change in HbA1c (Case 19 and 24), one (Case 20) whose whom HbA1c improved, and the remaining three (case 21, 22, and 23) whom HbA1c experienced a deterioration in HbA1c over follow-up (Figure 24). In contrast, all MET participants had clinically significant improvements in HbA1c during follow-up, and for the four participants for whom 12-month follow-up data was available the clinical significant decrease was present at 12-month follow-up. The improvement for one (Case 26) of these MET participants, however, is more likely attributable to change in medication, rather than improved diabetes self-management (Figure 24). It should also be noted that baseline data was not available for Case 29.

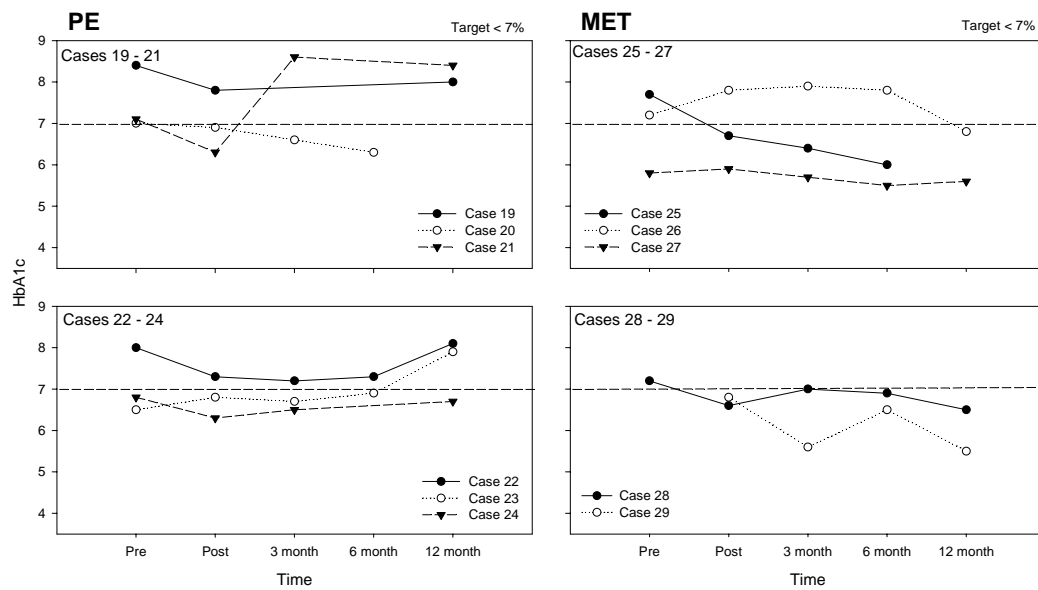


Figure 24. Average blood glucose

Data from SMOBG. Three PE participants (Cases 20, 21 and 24) did not engage in SMOBG at baseline, limiting the conclusions that can be drawn regarding a change in their self-monitored blood glucose over the course of the study. Results from the remaining PE participants, however, were mixed (Figure 25).

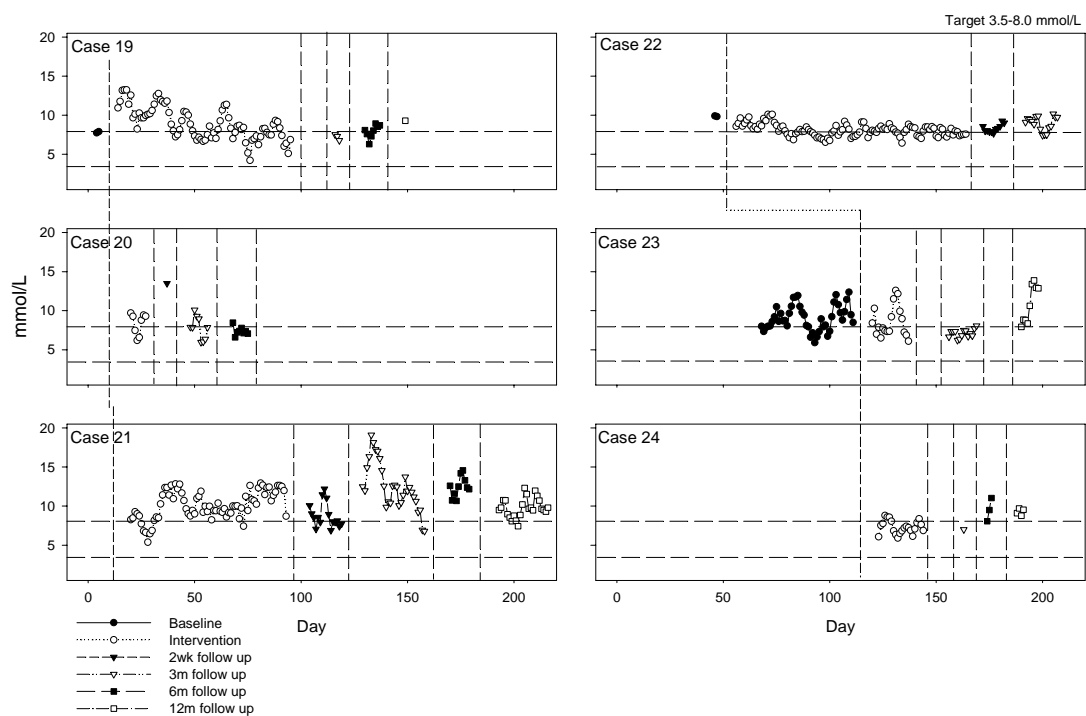


Figure 25. Self-monitored blood glucose level – PE

There was a decrease in self-monitored blood glucose during PE for two participants (Cases 19 and 22), with both obtaining blood glucose results within the target range. Yet, for another participant (Case 23), there appears to have been no change in self-monitored blood glucose level during PE.

Only one MET participant (Case 26) did not engage in SMOBG at baseline (Figure 26), although baseline data were also limited for one other MET participant (Case 27). The results, however, suggest that there was a downward trend in self-monitored blood glucose during MET for two (Cases 28 and 29) of the MET participants, both of whom obtained blood glucose results in the target range. Furthermore, although the results fluctuated over time, both of these participants had lower self-monitored blood glucose at 12-month follow-up, with Case 28 obtaining results all within the target range.

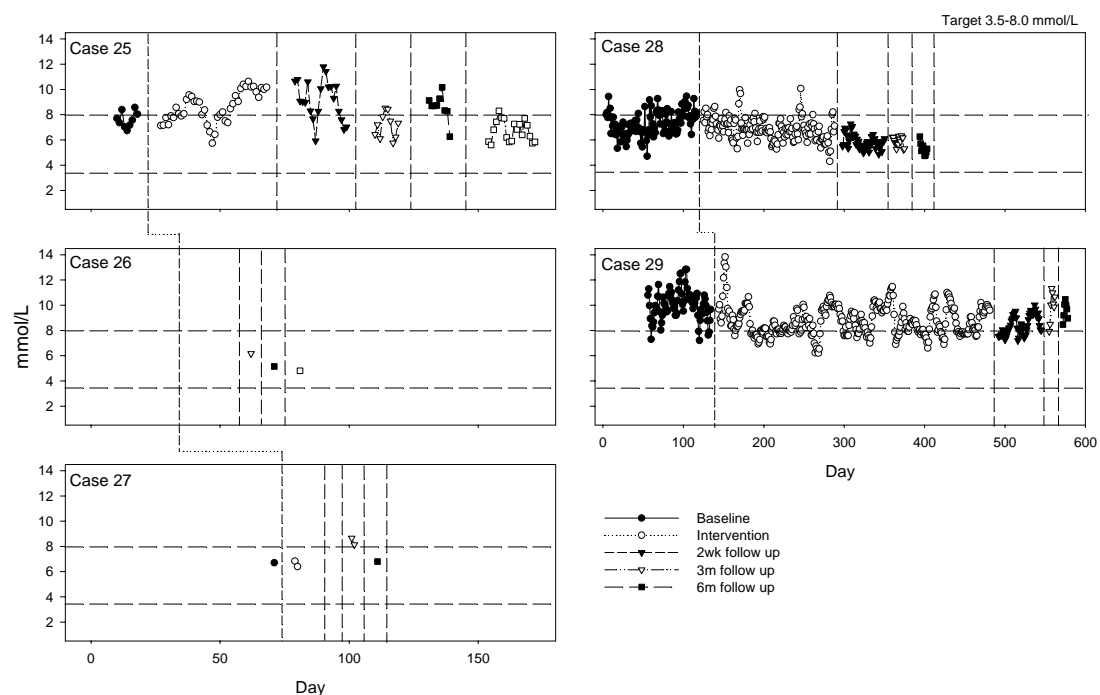


Figure 26. Self-monitored blood glucose level – MET

For Case 25 there appears to have been a downward trend in self-monitored blood glucose results in the middle stages of MET. Yet, this was not maintained during the later stages of MET, or during 2-week and 6-month follow-up, although results at 3- and 12-month follow-up were lower (mostly within the target range) than at baseline.

Where there are sufficient data, it appears that MET may have contributed to a decrease in blood glucose as measured by SMOBG for at least two MET participants, which tended to be maintained during follow-up. Overall, however, there were mixed results obtained for both PE and MET.

Lipids

Mixed results were also obtained for the PE participants' lipids. There were clinically significant improvements in lipids for three PE participants (Case 19, 20, and 21) post-PE, but a deterioration (Case 23), or little or no change (Case 22 and 24), in lipids for the other three PE participants (Figure 28-32). The improvement in lipids was maintained for two of the participants (Case 19 and 20) during follow-up. In contrast, all but one (Case 29), whose lipids were unchanged, of the MET participants had clinically significant improvements in their lipids post-MET (Figure 27-31). Three MET participants maintained the improvements in lipids at 3- (Case 26 and 27) and 6-month (Case 25) follow-up, and one (Case 26) participant had further improvements (especially in the risk ratio) over follow-up.

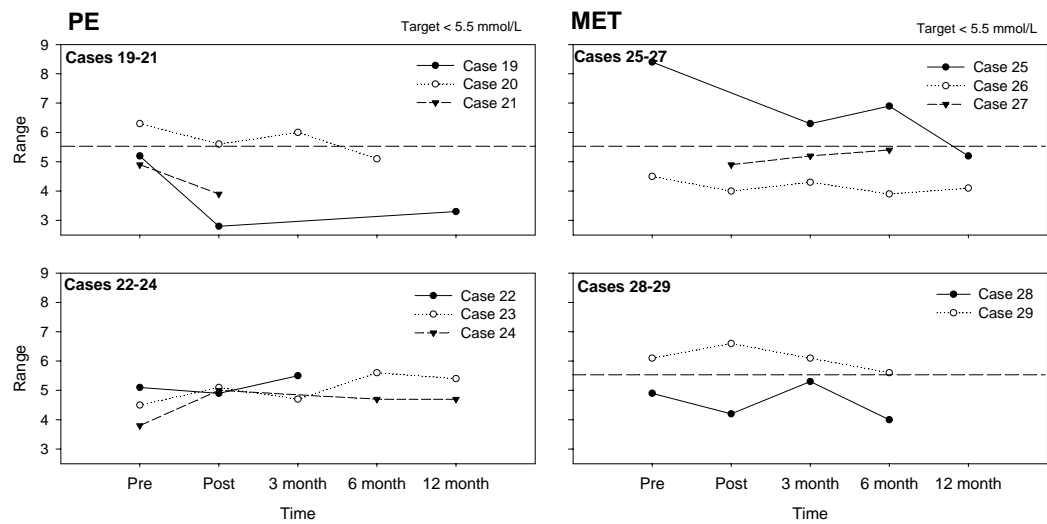


Figure 27. Total cholesterol

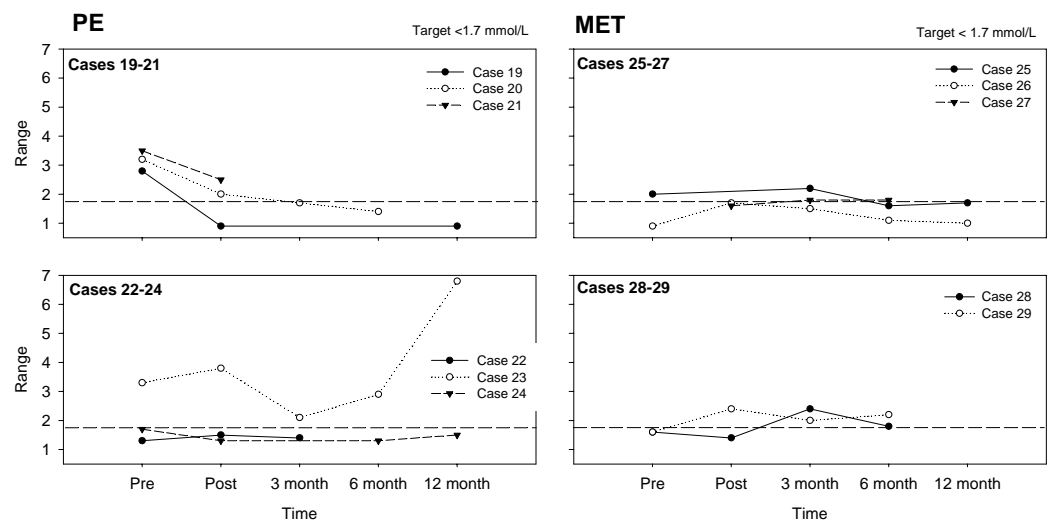


Figure 28. Triglycerides

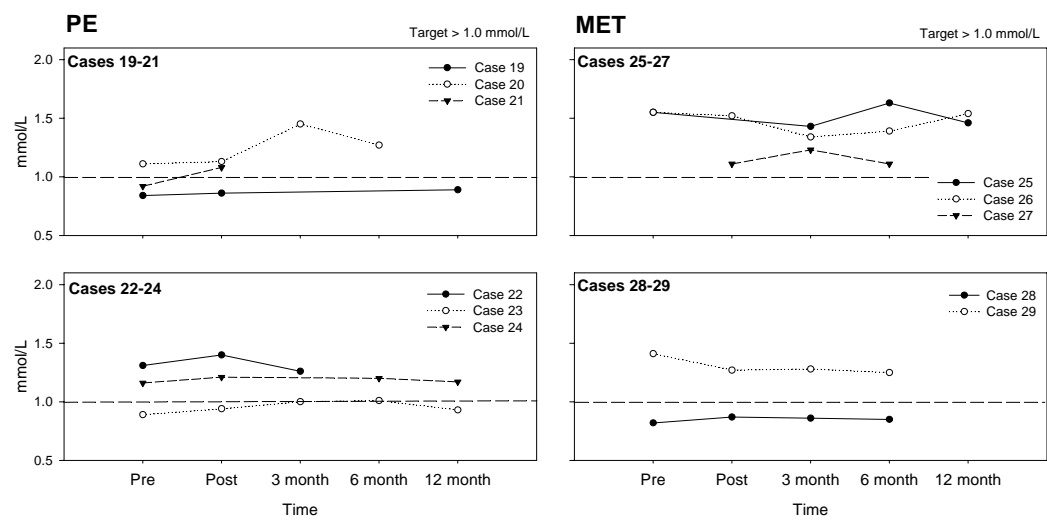


Figure 29. HDL cholesterol

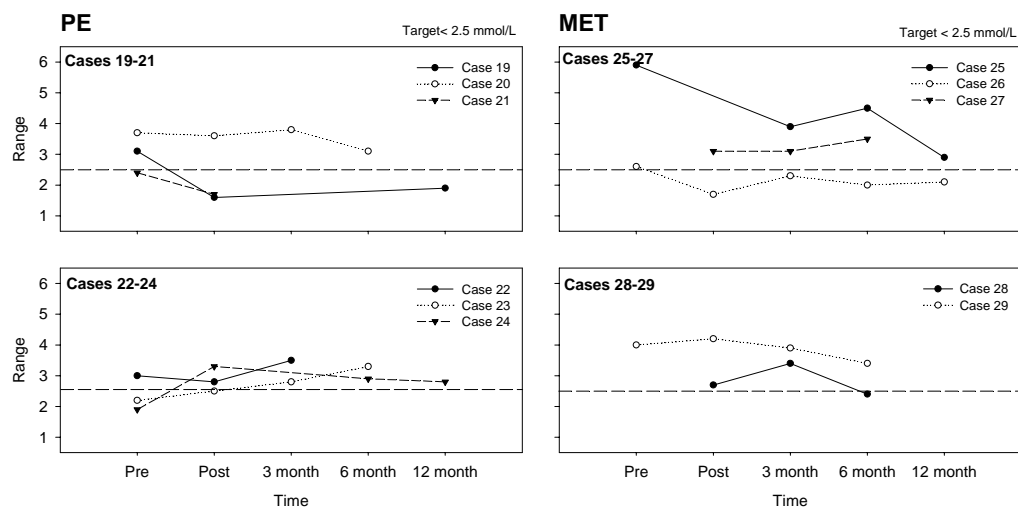


Figure 30. LDL cholesterol

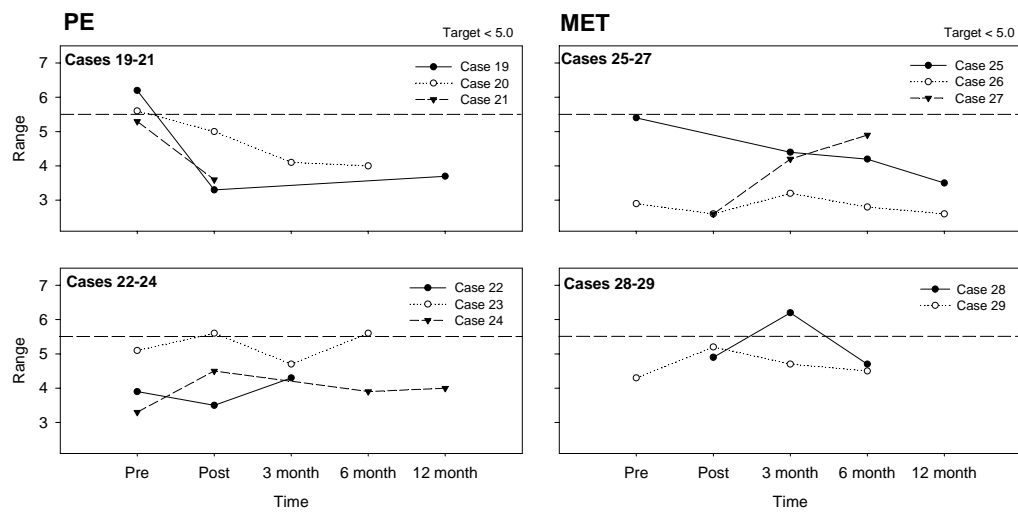


Figure 31. Risk ratio

Intermediate Process Variables

Diabetes self-management goals

All PE and all but one of the MET, participants selected dietary compliance as their diabetes self-management goal (Table 25). This is consistent with their referral to a Dietician, and is in contrast to Study 1 in which increased SMOBG was the most frequent goal. Increased exercise was the next most frequent goal selected by both PE (n=2) and MET (n=3) participants, although three MET participants also selected weight loss as a goal.

Table 25. Diabetes self-management goal

Goal	PE	MET
Increase SMOBG	1	0
Increase exercise	2	3
Dietary compliance	6	4
Regular eating	1	1
Weight loss	0	3

Dietary compliance. The data do not support PE as a means of improving dietary compliance, with mixed results for PE participants (Figure 32). The data suggest that two participants (i.e., Case 19 and 22) improved their dietary compliance during PE, although the improvement in dietary compliance does not appear to have been maintained beyond the end of PE.

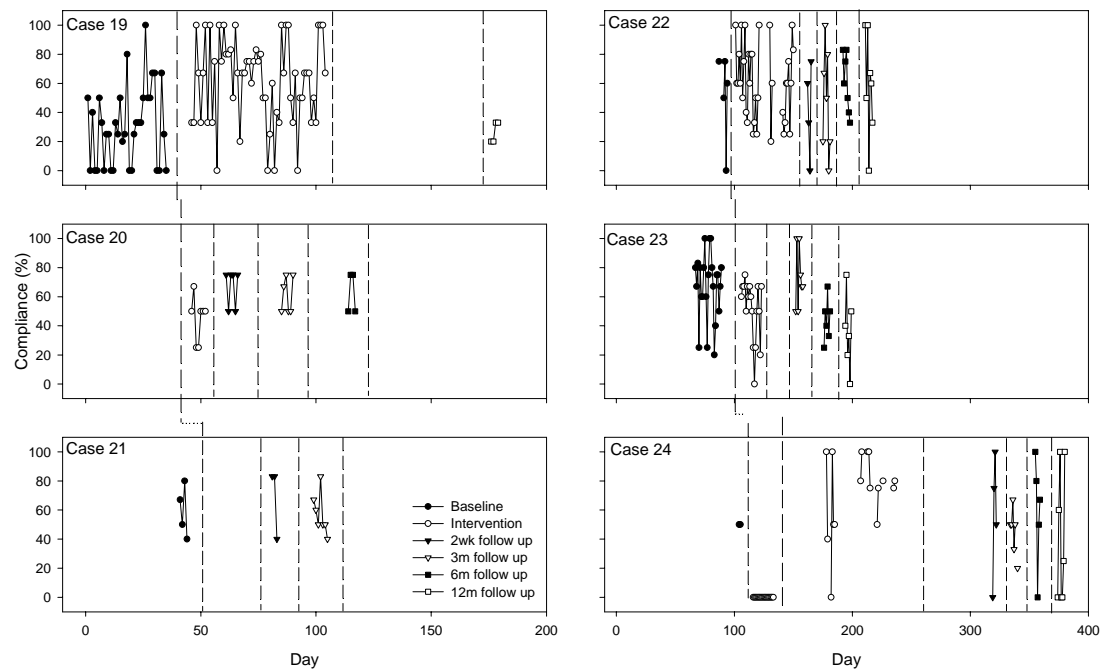


Figure 32. Self-management goal: dietary compliance – PE

For two PE participants (Cases 23 and 24), however, dietary compliance appears to have deteriorated with PE. The data are less clear for the remaining two PE participants (Case 20 and 21) due to inconsistent self-monitoring of food.

Although Case 21 did not record her food intake during PE (or at 6- and 12-month follow-up), there does not appear to have been any change in dietary compliance from baseline to 2-week and 3-month follow-up (Figure 32). Case 20, on the other hand, did not self-monitor his food during baseline, so it is not possible to determine if there was an improvement in dietary compliance with intervention. Yet, he began (although inconsistently) to record his food intake during PE and maintained this throughout follow-up, indicating that perhaps he was paying more attention to his food intake. The data available suggest 50% or more compliance on five out of seven days recording occurred during PE, with compliance improving to 50% or more on all days in which recording occurred during follow-up.

In contrast, the data suggest that MET may have contributed to improved dietary compliance (Figure 33). Three (Cases 25, 26 and 29) of the four MET participants who selected dietary compliance as a goal appear to have improved their compliance during MET. Furthermore, the improvements in dietary compliance appear to have been maintained (Case 29) or further enhanced (Cases 25 and 26) during follow-up.

Although Case 28 did not self-monitor her food intake during baseline, preventing conclusions being drawn regarding any changes in dietary compliance with intervention, that she commenced self-monitoring during MET is possibly an indication that she began to pay more attention to her diet during MET. Self-monitoring during follow-up indicates that there were improvements in dietary compliance from that achieved during MET up to 6-month follow-up.

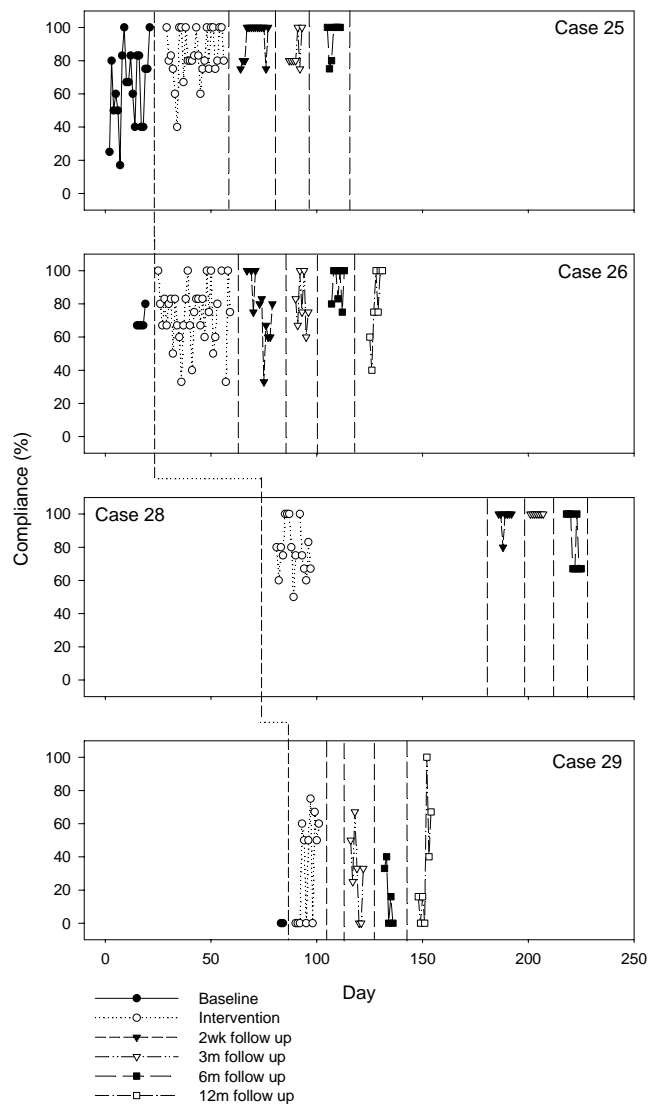


Figure 33. Self-management goal: dietary compliance – MET

Exercise. The data also do not support PE as a means of increasing the participants' exercise (Figure 34). Although Case 23 appears to have been achieving, or exceeding, his exercise goal on approximately 50% of days at baseline, his bicycling appears to have decreased during PE. He did not self-monitor his exercise during 2-week follow-up, but it appears that at 3-month follow-up his bicycling was at a similar level to as at baseline, and that at 6- and 12-month follow-up, his bicycling decreased to below baseline.

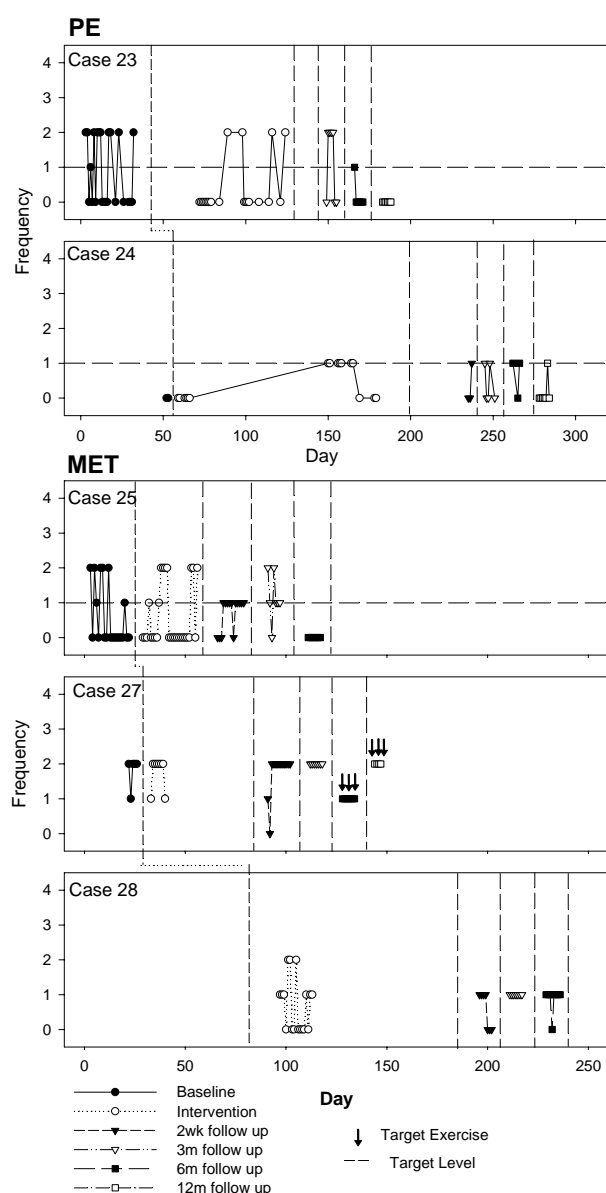


Figure 34. Self-management goal: increase exercise

Case 24 did not regularly self-monitor her exercise, however, it appears from the data available, that at baseline and the early part of PE she was not walking for exercise, but in the later stage of PE, she was able to achieve her goal of walking once per day, although this increase does not appear to have been maintained during the remainder of PE. Data during follow-up suggest that up to 6-month follow-up she was achieving her goal on approximately 50% of days, although at 12-month follow-up her walking appears to have decreased to a similar level to baseline.

The effectiveness of MET as a means of increasing exercise is unclear (Figure 34). While baseline data suggest that Case 25 was achieving his goal of bicycling daily approximately 50% of days, the frequency of bicycling does not appear to have increased during MET. Unfortunately he experienced a back injury on the third day of 2-week follow-up necessitating a change in goal to a daily walk for exercise. He appears to have achieved this goal on most days during the 2-week follow-up period, and data at 3-month follow-up (during which the goal was to exercise daily by either walking or bicycling), suggest that he further increased his exercise. Data at 6-month follow-up, however, suggest that the increase in exercise was not maintained, and 12-month follow-up data were not available.

Self-monitoring indicates that Case 27 was exceeding her goal of engaging in water-based exercise twice per week at 6- and 12-month follow-up, but that prior to this (i.e. baseline through to 3-month follow-up) she was not engaging in this type of exercise. Therefore, it is unclear if the increase in exercise was due to MET or some other factor that came into play by 6-month follow-up.

Case 28 did not record her exercise during baseline, so conclusions regarding any changes in exercise from baseline cannot be drawn. Yet, she did start recording her exercise during the earlier stages of MET, which perhaps suggests that this at least became more of a focus for her. The data collected suggest that during MET she was approximating her goal of walking six days per week. Unfortunately, she did not continue to record her exercise, so it is unclear as to what happened for the remainder of MET. Data at 2-week, 3- and 6-month follow-up, however, suggest that she was continuing to maintain the increase in exercise at the target level.

Regular eating. The data also do not support PE as a means of increasing the regularity of eating (Figure 35). Case 19 appears to have already been achieving his goal of eating regularly (i.e., six times per day) during baseline on approximately 25% of days, although there was considerable variability (range 0-7) in the number of meals/snacks per day. During PE, however, there appear to have been only two days in which he achieved his goal, although there appears to have been some reduction in the variability of the number of meals/snacks per day during PE. It is unclear what occurred beyond PE as self-monitoring did not occur during follow-up, with the exception of four days at 12-month follow-up in which the number of meals/snacks appears to have increased to near target.

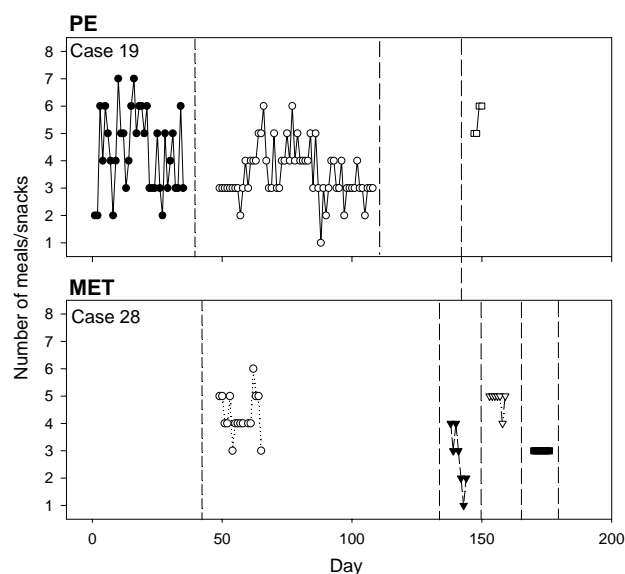


Figure 35. Self-management goal: regular eating

Unfortunately Case 28 did not record her eating during baseline, so conclusions as to the effect of MET on increasing the regularity of eating cannot be drawn (Figure 35). Yet, she did commence self-monitoring her eating during MET, which suggests that she at least may have started paying more attention to her eating,

although the number of meals/snacks consumed per day was less during follow-up than during MET, suggesting that any improvements may not have been maintained.

Weight loss. Three MET participants also selected weight loss as one of their goals. While the lack of multiple data points does not enable a true single-case design analysis, the results were still graphed for analysis (Figure 36). The data suggest that, as in Study 1, MET did not have any significant effect on the participants' weight, with all participants' weights remaining fairly stable over the course of the study.

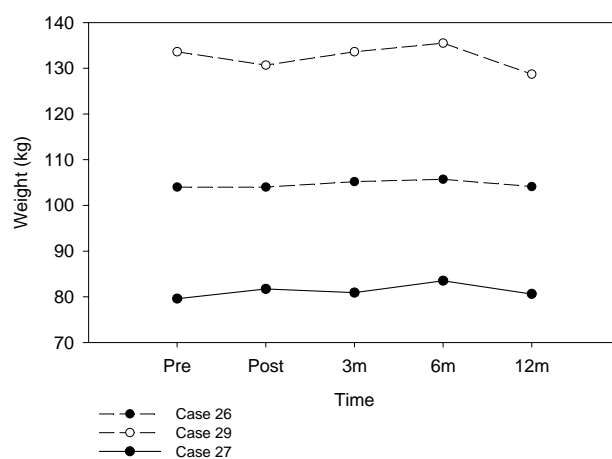


Figure 36. Self-management goal: weight loss

Increase SMOBG. Case 21 also had the goal of increasing SMOBG to four times per day, which she appears to have achieved during PE (Figure 37). SMOBG increased from no testing at baseline and in the earlier stages of PE to approximately 50% of days during PE. This increase was maintained at 2-week follow-up, with further increases in the frequency of SMOBG at 3-, 6- and 12-month follow-up. She achieved the goal of testing four times per day on more than 50% of days at 3-month follow-up, but did not achieve this goal at 6-month follow-up, and achieved this less frequently at 12-month follow-up.

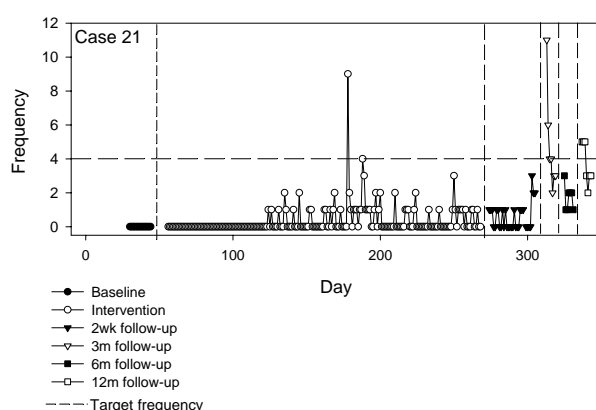


Figure 37. Self-management goal: increase SMOBG

Psychosocial measures

PMDI. Most of the PE participants considered PE to be as effective as the TAU they received at baseline (n=4), with one participant considering PE more effective, and one participant (Case 19) considering PE less effective, than TAU at baseline (Table 26). Two participants (Case 22 and 24), however, considered PE more effective than the TAU they received at 12-month follow-up. In contrast, two MET participants (Case 25 and 26) considered MET more effective than the TAU they received at baseline, with the remainder considering both interventions similarly effective (Table 26). All, but one participant (Case 28) considered MET as effective as the TAU they received at follow-up.

Table 26. Clinically significant change on the PMDI, PAID and DKT – PE and MET

	PMDI				PAID		DKT	
	<i>Treatment Effectiveness</i>	<i>Seriousness</i>						
	Post	12 month	Post	12 month	Post	12 month	Post	12 month
PE								
Case 19	+2.77				+5.84	-4.43		+6.59
Case 20					+3.02		+2.56	
Case 21								
Case 22		-3.09	+3.02	-2.01	+2.82	-2.62		-2.56
Case 23		+3.93			-3.83	-2.42		+3.84
Case 24	-5.49	-7.32	+2.01	-2.01		+4.23		
MET								
Case 25	+4.39		+2.01					
Case 26	+2.28			-2.01		-2.42		-2.75
Case 27			-3.52	-4.53			+2.56	-2.56
Case 28		+3.42		-5.03	-8.06	-7.65		
Case 29					-3.22	-4.23		

+ =clinically significant increase in score (i.e., RC>1.96) from baseline

- =clinically significant decrease in score (i.e., RC>1.96) from baseline

NB: empty cell means there was no clinically significant change in the score from baseline

For most PE (n=4) and MET (n=3) participants, their concern about the seriousness of their diabetes did not change post-intervention (Table 26). At 12-month follow-up, however, three of the MET participants (Case 26, 27 and 28) showed a decrease in concern, whereas there was no change in concern for all the PE participants.

PAID. Three PE participants (Case 19, 20 and 22) experienced a deterioration in their emotional adjustment to diabetes post-PE, whereas two MET participants (Case 28 and 29) experienced an improvement in their emotional adjustment to diabetes post-MET (Table 26). Additionally, at 12-month follow-up three MET

participants' (Case 26, 27 and 28) emotional adjustment to diabetes showed an improvement from baseline, whereas this was the case for only one PE participant (Case 23), with most (n=4) PE participants' emotional adjustment remaining unchanged.

DKT. Only one participant from PE (Case 20) and MET (Case 27) had an increase in knowledge about diabetes post-intervention, with no change in diabetes knowledge for the remaining participants (Table 26). Whilst at 12-month follow-up one participant from PE (Case 22) and MET (Case 26) had a decrease in knowledge about diabetes from baseline, suggesting they had forgotten some facts about diabetes, two PE participants (Case 19 and 23) also had increased diabetes knowledge. Nevertheless, the majority of PE and MET participants showed little change in their knowledge about diabetes throughout the study.

SOCRATES. All, but one (who was in the maintenance stage of change), of the PE participants were in the action stage of change at baseline, suggesting that they were already engaging in behaviour change related to diabetes self-management. In contrast, the MET participants were spread between the contemplation (i.e., ambivalent about behaviour change, n=1), preparation (i.e., ready to engage in behaviour change, n=2), and action (n=2), stages of change. The motivation for change for three PE (Case 22, 23, and 24) and three MET (Case 27, 28 and 29) participants' appears to have increased post-intervention, although one PE participant (Case 19) appears to have become less motivated to change (Figure 38). At 12-month follow-up, most (n=4) MET participants' motivation was the same as post-intervention, with one MET participant's motivation to change increasing further

Case 27). Three PE participants' (Case 22, 23, and 24) motivation decreased at 12-month follow-up and two PE participants' (Case 19, 21) motivation increased at 12-month follow-up.

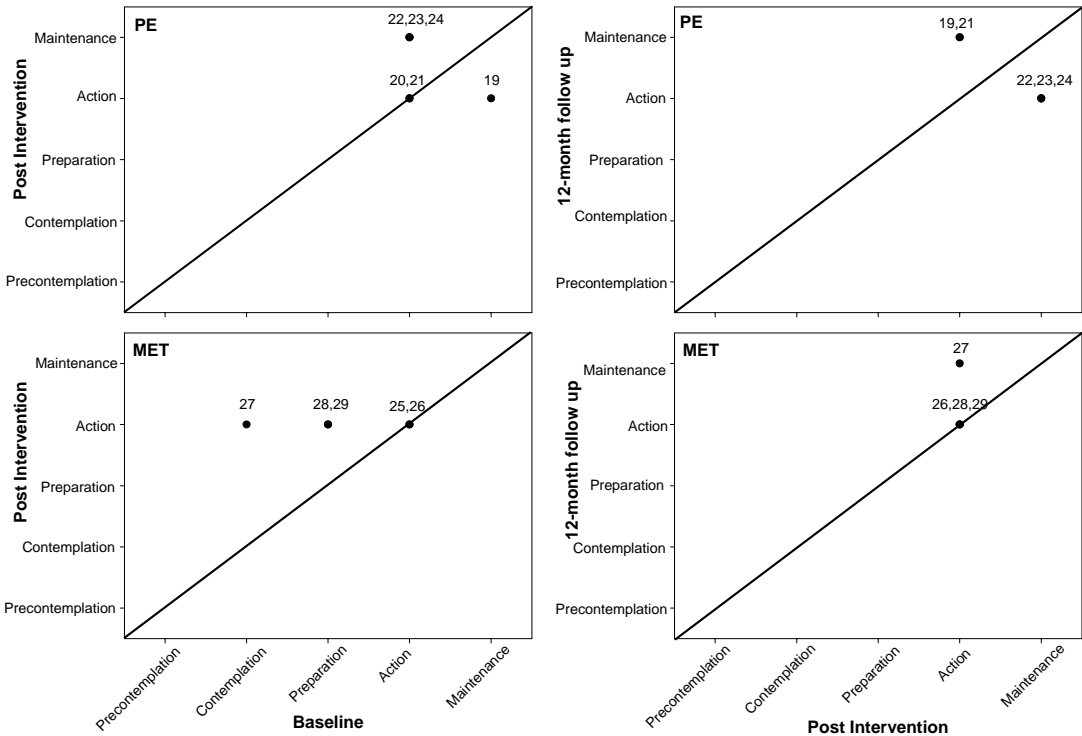


Figure 38. SOCRATES: Stages of change

Treatment Credibility

Both interventions were rated highly overall by participants, with mean total credibility ratings on the TEI of 89% and 94% for PE and MET respectively (Table 27). This suggests that both interventions were considered to have high credibility.

On only four items of the TEI (items 4-7) was MET rated less than six out of seven. These items related to the risks associated with the treatment, how much the procedures were liked, how effective the treatment was likely to be, and how likely it

was to make permanent improvements. In contrast, PE was rated less than six out of seven on all but two items (i.e., items 9 and 10, which relate to the discomfort experienced during the treatment and the participant's general reaction to the treatment). The lowest rating (score of 3) received was for PE on item 7, which relates to how likely the intervention was to help make permanent improvements.

Table 27. TEI: summary of results

Item	Mean		Range	
	PE	MET	PE	MET
1	5.500	6.800	6–7	6–7
2	6.500	6.800	4–7	6–7
3	6.333	6.800	4–7	6–7
4	6.333	6.400	4–7	4–7
5	5.500	6.600	4–7	5–7
6	5.833	6.400	4–7	4–7
7	5.667	5.800	3–7	4–7
8	6.500	6.800	4–7	6–7
9	6.833	7.000	6–7	7
10	6.000	6.800	4–7	6–7
Total	89%	94%	77-100%	81-100%

Treatment Integrity

All of the audiotapes reviewed by the independent rater, blind to condition, were accurately identified as either PE or MET sessions. This is consistent with the findings of Study 1 and suggests that these were distinct interventions.

Resource Utilisation

Similar to Study 1, MET required more appointments than PE (Table 28). The MET appointments also tended to be of longer duration than the PE appointments, although the difference between PE and MET does not appear to have been as large as in Study 1, with PE in Study 2 tending to be longer than that in Study 1 (MET mean of 38.9 minutes compared to PE mean of 22.9 minutes).

Table 28. Resource utilisation

Appointment	PE	MET
Total attended	2.714	4.000
Duration (mins)	38.882	42.750
Extra	1.667	2.2
Missed	1.0	0.4

Again similar to Study 1, PE participants tended to miss more appointments than the MET participants (Table 28). Unlike Study 1, however, MET participants appear to have attended more extra appointments during follow-up than PE participants (Table 28), although the extra appointments for the MET group were all attributable to only one participant.

Discussion

Similar to Study 1, there were clinically significant improvements in diabetes outcome (HbA1c and lipids) following MET provided by dietitians (Hypothesis 1). The improvements in metabolic control, however, occurred during the course of follow-up, rather than immediately post-MET. This is consistent with Hettema et al's (2005) finding that the effect of MI may be delayed for behaviours such as diet and exercise due to 'sleeper effects' (i.e., effects which accumulate and take time to produce measurable change).

PE participants also appear to have had improved blood glucose (i.e., HbA1c), and, to a lesser extent, improved lipids post-PE. In contrast to the MET participants, the PE participants did not experience further improvements in metabolic control (HbA1c or lipids) over follow-up.

These findings are similar to those reported by Burg et al (2007) who compared MI to usual care, both provided by dietitians with patients newly diagnosed with Type 2 diabetes and found that patients in both groups improved their saturated fat intake levels and HbA1c, with no significant difference between the groups. The measures in that study, however, were obtained only up to 6-weeks post-intervention. It is possible, had Burg et al (2007) had extended their follow-up, that they may have found continued improvements for the MI group, given the results of the current study and Rubak et al's (2005) meta-analysis of MI and disease which that the likelihood of finding an effect for MI increased with longer follow-up.

Also consistent with the findings of Study 1, there is evidence that MET led to somewhat improved diabetes self-management (Hypothesis 2), in this case via dietary compliance. In contrast, the data do not support PE as a means of improving diabetes self-management.

The results of the psychosocial measures were also similar to the findings of Study 1. Most PE participants considered PE as effective as the TAU they received at baseline and 12-month follow-up, whereas more mixed results were obtained for the MET participants. While some MET participants considered MET more effective than TAU at baseline, most considered MET as effective as the TAU they received at 12-month follow-up. Both interventions were also rated highly in terms of credibility (Hypothesis 4). MET, however, was consistently rated (on TEI item scores) higher than PE.

Most of the participants in both interventions experienced low to moderate levels of diabetes-related distress at baseline, with the exception of one MET participant who was near the diabetes burn-out range. In contrast to Study 1, the MET participants' emotional adjustment to diabetes appears to have either remained unchanged or improved (post-MET and at 12-month follow-up), whereas half of the PE participants experienced a deterioration in emotional adjustment to diabetes post-PE (Hypothesis 6). The reason for this difference in results between Study 1 and 2 is unclear.

The MET participants experienced a decrease in concern about the seriousness of diabetes and future complications (Hypothesis 6). In Study 2, however, this did not occur until 12-month follow-up, whereas there was a decrease in concern post-intervention for the MET participants in Study 1. A possible reason for this difference is that due to the ‘sleeper effects’ of dietary change mentioned above, the participants in Study 2 may have experienced delayed improvements in diabetes outcome, and hence the decrease in concern about their diabetes was also delayed, compared to the participants in Study 1 for whom improvements in diabetes outcome were more immediately obvious post-MET.

As in Study 1, there appears to have been a differential effect on readiness for change (as measured by the SOCRATES) with the two interventions. All of the MET participants’ motivation to change either remained the same, or increased immediately post-intervention and at 12-month follow-up (Hypothesis 7), whereas some PE participants’ motivation decreased.

Additionally, for both interventions, there was no clinically significant change in most participants’ knowledge about diabetes (DKT) in Study 2 (Hypothesis 8). This contrasts with the results of Study 1, which found that clinically significant increases in four of the MET participants’ knowledge about diabetes at 12-month follow-up.

Thus, although the number of participants in Study 2 is small (n=6 for PE, n=5 for MET), the results lend further support to the findings of Study 1. In particular, the replication of the findings of Study 1 with dietitians conducting the intervention

provides evidence for the generality of the findings of Study 1. Additionally, treatment integrity data suggests that MET was successfully applied by the dietitians, and again after relatively brief training, followed by supervised practice.

The MET participants in Study 2 tended to have had diabetes diagnosed for a shorter duration, had lower baseline blood glucose and fewer diabetes-related complications than the MET participants in Study 1. They also had different diabetes self-management goals, tending to focus on dietary compliance and increased exercise, compared to the MET participants in Study 1, who tended to focus on increasing SMOBG. Thus evidence is provided that MET may effectively be provided by dietitians as well as nurse educators, and may be effective for individuals with varying histories of diabetes diagnosis, control and disease progression, and with a variety of self-management goals, in particular dietary compliance and increased SMOBG.

As in Study 1, the conclusions that can be drawn from the current study are highly tentative for the similar reasons as in Study 1. Specifically the limitations of Study 2 include the small sample size, variability in the goals for change selected by the participants and in the data within individuals, contributing to a lack of stable baseline data, lack of random assignment to condition and control over phase change criteria, and reliance on visual analysis of the data.

STUDY 3: EVALUATION OF TRAINING

The aim of Study 3 was to evaluate the effectiveness of the MI training provided in Study 1 and 2. This involved an evaluation of the effects on practitioner, and patient, within session behaviour after the practitioner's had received MI training comprising a two day (12 hours) workshop and supervised practice.

Knowles (1973) developed a theory of adult education, based on four main assumptions, each of which have implications for psychotherapy training (Kalafat & Neigher, 1983), and appear to be consistent with MI theory. The first assumption is that adults experience an increasing need to be self-directed, and when in situations in which they are not allowed to be self-directed, they react with resistance, which may interfere with learning. Training should therefore actively engage adult trainees in the learning process using experiential approaches, and allow the trainees to adapt the new approach into their own style, rather than be passive-recipients who are required to conform rigidly to the new method.

The second assumption is that "as individuals mature, they accumulate an expanding reservoir of experience that renders them a rich resource for learning and provides them with a broadening base to which to relate new learning" (Kalafat & Neigher, 1983, p.97). The trainer should therefore act as a facilitator (Rogers, 1969), who draws knowledge and skill out of the trainee, rather than as an instructor.

The third assumption is that training must take the adult's readiness to learn into account, which requires attending to, or stimulating, the trainee's motivation to learn, with the recognition that adults learn what they want or need, not necessarily what they ought to learn. Furthermore, Knowles (1973) fourth assumption is that adults' motivation to learn is problem-centred rather than content centred, so that an adults' motivation to learning is based on a current problem they need to solve. Kalafat and Neigher (1983) point out that, as a result of this problem-centred focus to learning, practitioners tend to 'have an applied, "show me the practical significance" attitude about training' (p.97).

Consistent with Knowles (1973) theory of adult education, research on the effects of training in psychotherapy provides evidence that training which involves active training elements such as practice (Froehle, Robinson & Kurpius, 1983; Hazler & Hipple, 1981; Iwata, Wong, Riordan, Dorsey & Lau, 1982), modeling (Kurpius, Foehle & Robinson, 1980; Robinson, Kurpius & Foehle, 1981) and feedback (Hosford & Johnson, 1983), is associated with changes in therapist behaviour (Bootzin & Ruggill, 1988). This has been found to be true for more complex therapist behaviours (Alberts & Edelstein, 1990) as well as specific therapist techniques such as the use of open-ended questions, reflections, and basic interviewing skills (Froehle et al., 1983; Hazler & Hipple, 1981; Iwata et al., 1982; Robinson & Cabianca, 1985).

There is also evidence that training in a workshop format (i.e., intensive practice-based training) can be effective. Milne, Keegan Westerman & Dudley (2000) found, after a brief in-service training programme in psychosocial interventions for severe mental illness for multidisciplinary mental health staff, that

there were positive changes in the participants' clinical practice. Similarly, Davis, Kvern, Donen, Andrews & Nixon (2000) found that a workshop for physicians on best practices in treating osteoporosis produced modest positive changes in the participants' clinical practice after the workshop. Additionally, Davis, Thompson, Oxman & Haynes (1992) in a review of continuing education for medical practitioners found that workshop based training was effective, particularly when the participant activity and feedback during the training was high. Furthermore, DeViva (2006) found that a 3- and 6-hour workshop for graduate students preparing for health care careers and practicing health practitioners (e.g., social workers, medicine, nursing) on techniques for increasing resistant clients' motivation were associated with significant change in participant behaviour in analogue role-plays immediately after training. Additionally, there was no difference in the effects between the students and health practitioners, suggesting that expert knowledge or clinical experience may not be a necessary prerequisite for benefiting from continuing education workshops. It should be noted, however, that the evaluation in these studies occurred soon after the training, so it is unclear as to whether the effects of training were maintained over time.

Earlier studies evaluating the outcome of training in MI (Rubel, Sobell & Miller, 2000) and those that have used treatment adherence ratings to assess treatment integrity (Bien, Miller & Burroughs, 1993; Carroll, Kadden, Donovan, Zweben & Rounsaville, 1994) also support the effectiveness of MI training. The results of these studies suggest a change in therapist behaviour post-training consistent with MI. These studies, however, used only global ratings of MI consistent and MI non-

consistent therapist behaviour, rather than measures of specific MI skills (e.g., frequency and type of reflections).

These results are supported by more recent studies (Brug et al., 2007; Miller & Mount, 2001; Miller et al., 2004) evaluating the effectiveness of MI training using the MISC, which operationalises the principles of MI and includes specific behaviour counts of therapist and client within session behaviour (Catley et al., 2006). These studies found that after training, comprising a two-day workshop on MI, health practitioners (probation counselors, alcohol and drug counselors, and dietitians) showed significant changes in their behaviour as therapists consistent with MI lasting up to eight months post-training, although Miller et al's (2004) findings suggest that the maintenance of changes post-training is dependent on feedback and/or coaching being included post-training.

In addition to demonstrating that there were positive changes in the practitioners' behaviour post-training, Miller et al (2004) also provided evidence of client within-session behaviour consistent with MI theory four months post-training, with less resistance and more change talk. This was only true, however, when the training was followed by feedback and/or coaching.

In summary, there is evidence that, with two days training, practitioners are able to develop an understanding of the spirit and method of MI. The effectiveness of MI training as a means of promoting both practitioner and client behaviour change consistent with MI theory, however, is significantly increased by adding feedback (e.g., from audio-taped practice) and/or coaching (Miller et al., 2004).

Yet, few studies on the effectiveness of MI evaluate the integrity of the MI provided (Burke et al., 2004). Miller, in a commentary on the Dunn et al (2001) meta-analysis (Rollnick, Miller, Heather, Longabaugh & Dunn, 2001), suggests ‘that appropriate assessment of MI practice is necessary in studies on MI in order to explore the effects of “true” MI practice, and that direct monitoring of practice is the gold standard, since self-reports of MI practitioners are unreliable’ (Burg et al., 2007, p.11). Additionally, as Dunn et al (2001) point out, without knowing what skill level is achieved through MI training, and the optimal training duration, it is difficult to estimate the cost-effectiveness of MI interventions.

The current study evaluated the effectiveness of MI training provided in Study 1 and 2, by evaluating the effect of MI training on both health practitioner and client behaviour in a real life clinical setting. More specifically, this involved evaluating health practitioners’ responses to MI training and the knowledge they acquired as a result of the training. Additionally, there was an evaluation of whether there was a change in the practitioners’ clinical practice (i.e., MI-consistent, use of specific MI skills), and whether this resulted in changes in the clients’ behaviour (e.g., less resistance, more change talk) within session.

Specific hypotheses were that, with two days training plus supervised practice, involving feedback and coaching, the practitioners’ would be more patient-centred during MET (Hypothesis 1), and that there would be more collaboration (i.e., agreement) between the practitioners and participants when setting intervention goals during MET compared to PE (Hypothesis 2). It was also hypothesised that the practitioners would demonstrate greater MI adherence (Hypothesis 3) during MET

and that this would be associated with more positive practitioner-client interactions within session (Hypothesis 4). Specifically, it was hypothesised that the practitioners would ask more open questions (Hypothesis 3a), and use more reflective listening (Hypothesis 3b) and MI-consistent responses (Hypothesis 3c) during MET compared to PE. Additionally, it was hypothesised that patients would show more signs of readiness to change (Hypothesis 4a), including engaging in increased frequency of change talk, and less resistance (Hypothesis 4b). Furthermore, it was hypothesised that two days training in MI only (i.e., with no supervised practice) would increase the practitioners' beliefs about the usefulness (importance) of MI to their work (Hypothesis 5), knowledge about MI (Hypothesis 6), and confidence in using MI (Hypothesis 7), but that the practitioners may not feel ready to practice MI without ongoing support in the form of supervised practice (Hypothesis 8).

Method

Procedure

Participants

Data collected in association with Study 1, involving the two DNEs, were used as part of Study 3. Additionally, another 13 diabetes health practitioners subsequently received the same training in MET as provided in Study 1, and were also included in the evaluation of training. The additional health practitioners were seven DNEs, five dietitians and three podiatrists. Of these, two specifically worked with Pacific Island People, two with Maori, and three with adolescents with diabetes.

Training

The training was similar to that conducted in Study 1 and 2, using the same trainers (i.e., two trainers experienced in training MI, one of whom was the author). The training was conducted over two days (12 hours total), and was consistent with ‘adult education models (Kolb, 1984, Knowles, 1973; Reece & Walker, 1997) which reflect domains of learning, the importance of experiential learning cycles, and the need to match teaching strategy to specific learning objectives’ (Doherty et al., 2000, p. 265). Hence, the training consisted of didactic teaching, modelling by the trainers, video-taped demonstrations, and role-playing (using everyday clinical experiences) with feedback. A list of topics covered in the training is provided in Appendix 8. Additionally, the health practitioners were referred to Rollnick, Mason and Butler (1999) as a resource book.

Considerable time was spent in training on the rationale for, and spirit and principles of, MI, with a view affecting cognitive change, such that there was a shift in practitioners’ perceptions about the importance of MI and whether it would be helpful and relevant to their practice. Another main focus of the training was on developing reflective listening skills. It was only after the practitioners had demonstrated increased proficiency in the basic skills of open-ended questions, affirmation, reflections and summarising, that any specific MI strategies were taught.

The process of training modelled the process (i.e., spirit, principles, skills and strategies) of MI, with the trainers conveying “a respect for and curiosity about the learning needs and perspectives” of the practitioners and facilitating a learning

environment that had “a collaborative, exploratory feeling” (Miller & Rollnick, 2002, p.186). The training was also consistent with the guiding principles for MI training suggested by Miller and Rollnick (2002). This included listening “to the experiences, concerns and expectations” (Miller & Rollnick, 2002 p.187) of the practitioners, expecting and tolerating disagreement and ambivalence, with focus on learning how to do MI (not just learning about it).

Design and Measures

The design of the study permitted the evaluation of training in MET based on ratings for the clinical practice of the DNEs in Study 1, plus the additional health practitioners trained subsequently. The additional data about the actual implementation of MET was available from the audiotapes collected and rated as part of Study 1. This permitted the analysis of both therapist and client data obtained from the same two DNEs when providing PE and then subsequent to them being trained in MET. In this context, therapist (and client) behaviour in PE constitute a baseline against which acquisition of MET skills can be compared.

Treatment integrity

In order to measure the consistency with which the therapists delivered the two interventions (PE and MET), they were trained to deliver, the independent rater from Study 1 rated one randomly selected audio-tape from each participant from Study 1 (i.e. PE: n=9, MET: n=9, total 18 audio-tapes) on the following scales:

Risk Factor Interview Checklist (RFIC). A measure of patient-centred interviewing, with a focus on enhancing “the practitioner’s ability to reinforce the patient’s active participation in planning, initiating and maintaining adaptive lifestyle change” (Nolan, 1995, p.17A). The RFIC was modified for the current study for use with diabetes and for rating of audio-tapes (Appendix 9). The RFIC consists of 15 items (two of which were omitted in the modification as they did not apply to the current situation), which cover factors included in medical school curricula on a patient-centred approach to clinical interviewing (Nolan, 1995). Each item reflects a behaviour consistent with a patient-centred approach and is rated on a 3-point scale as 1, not demonstrated; 2, partially demonstrated; or 3, fully demonstrated.

MET Audit. A rating scale to audit MET sessions (Sellman et. al., 1996) which was modified for use with diabetes (Appendix 10). The MET Audit consists of 10 items reflecting key MI skills and behaviour consistent with an MI approach. Each item is rated on a 5-point scale in terms of how much it occurred, from 1 (not at all) to 5 (extremely).

As a reliability check, the author also rated the audio-tapes using the above scales. Intra-class correlations (ICCs), using a two-way mixed effects model (Shrout & Fleiss, 1979), were calculated for item and total scores of each rating scale. An ICC greater than .70 was considered acceptable reliability, with a coefficient of .40-.59 considered moderate, .60-.79 high, and greater than .80 considered excellent reliability (Landis & Koch, 1977).

The ICCs for the total score on the RFIC and MET Audit were both greater than .90 (Table 29), suggesting excellent reliability between the two raters for the total score on these scales. The ICCs for item scores suggested acceptable reliability (i.e., >.70) for eight of the thirteen items on the RFIC and seven of the ten items on the MET Audit (Table 29). Of those items with an ICC less than .70, only one item on the RFIC (item 2) and MET Audit (item 9) obtained an ICC less than .40, suggesting less than moderate reliability. These items refer to the patient being explicitly invited to collaborate in assessing their readiness to begin or continue with lifestyle change (RFIC item 2) and how much the practitioner actively explored non-diabetes issues of the patient in depth (MET Audit item 9).

Table 29. Intra-class correlations – RFIC and MET Audit

Item	RFIC	Met Audit
1	.51	.68
2	.35	.84
3	.70	.94
4	.79	.81
5	.86	.63
6	.95	.84
7	.85	.76
8	.74	1.00
9	.88	.23
10	.67	.74
11	.88	
12	.47	
13	.62	
Total	.96	.92

The frequency of ratings on individual items on both scales was calculated. Additionally, statistical tests on inferential confidence intervals (Tryon, 2001) for total and item scores were used to evaluate statistical difference and equivalence between PE and MET ratings.

Therapy process

The independent rater was also asked to code for type of resistance behaviour observed, or any signs of readiness to change (Appendix 11). The frequency of occurrence of each type of resistance behaviour and signs of readiness for change (from the independent ratings) were then graphed. Again, as a reliability check the author also recorded this and ICCs (two-way mixed effects model) were calculated to compare the two sets of ratings.

There was also acceptable reliability for the total number of signs of resistance behaviour and of readiness for change (Table 30). The reliability was also excellent for the signs of readiness across cases, but only moderate for the signs of resistance (Table 30).

Table 30. Intra-class correlations – signs of resistance and readiness to change

	Resistance	Readiness
Individual cases	.44	.84
Total	.74	.97

Furthermore, all PE (n=22) and MET (n=36) audiotapes from Study 1 were transcribed and analysed using the MISC version 1.0 (Miller, 2000), a measure of proficiency in using MI, which also includes measures of client behaviour that are predictive of client behaviour change (Amrhein, Miller, Yahne, Palmer & Fulcher, 2003). The MISC is currently considered ‘the “gold standard” for measuring MI-consistent behaviour’ (Burke et al., 2004, p.315). Madson and Campbell (2006), however, in their review of measures of fidelity in MI suggest that, while ‘the MISC appears useful for deconstructing the interaction between clients and therapists, further examination of the psychometric properties is needed’ (p.69).

In the current study, only the Behaviour Counts (therapist and client) section of MISC was used. Full MISC coding, which requires at least three passes through an audio-tape, requires considerable training time for raters as well as time performing the actual coding. For example, Moyers, Miller and Hendrickson (2005) report that an average of 40 hours instruction was needed to achieve proficiency in rating with the MISC, and Tappin et al (2002) report that it can take up to four hours to evaluate a single sessions using the MISC. Instead, in the current study, coders (i.e., two post-graduate clinical psychology students, blind to condition) were trained to code the therapist and client behaviour according to the MISC using transcripts of each session. Coding from transcripts, rather than the audio-tapes, facilitated consistency between coders as each client or therapist utterance and code was readily available for examination. Thus, to maintain reliability of coding, the author reviewed the coding of one in six (i.e. 15%) of transcripts and any discrepancy in coding was discussed with the coder. This approach of using transcripts to code MI practice using the MISC was also utilised by Brug et al (2007), although they only analysed transcripts

from the first 15 minutes of the audio-taped sessions and did not include client behaviour in their analysis.

The following MISC summary scores were calculated from the behaviour counts:

Ratio of reflections to questions. The ratio of the number of reflective responses to the total number of questions asked.

Percent open questions. A ratio in which the numerator is the number of open questions asked, and the denominator is the total number of questions asked (open + closed).

Percent complex reflections. A ratio in which the numerator is the number of paraphrase + summarise reflections, and the denominator is the total number of reflections.

Percent MI-consistent responses. A ratio in which the numerator is the number of MI-consistent responses (MICO) and the denominator is the MICO plus MI-inconsistent responses (MIN).

Percent client change talk (%CCT). A ratio in which the numerator is the number of client change talk responses, divided by the sum of client change talk responses plus client resist change responses. The total %CCT was calculated as well as the %CCT for each third of sessions as the absolute level of %CCT is less

informative than the pattern of change in %CCT over the course of the session (Miller, Moyers, Ernst & Amrhein, 2003), with increasing %CCT over the course of a session associated with behaviour change.

The MISC summary scores for PE and MET were graphed. Additionally, statistical tests on inferential confidence intervals (Tryon, 2001) were used to evaluate statistical difference and equivalence between the DNE's MICO and MIN behaviour during PE and MET. Furthermore, the therapist behaviour counts were graphed for each DNE post-training (i.e., during MET), enabling evaluation of the DNE's use of each of these key MI responses over time (i.e., with supervised practice and feedback).

Lastly, data from the Goals for Change Checklist (GCC) from Study 1 were used to calculate the degree of collaboration (i.e., agreement on goals for change) between the DNE and participants. For analysis, the percentage agreement over time for each DNE was graphed separately, thus creating a multiple-baseline design.

Trainees' ratings and knowledge

The 13 diabetes health practitioners who received subsequent training in MET completed the following ratings pre- and post-training:

Importance. How important MET was for enhancing diabetes self-management on a 1-10 scale, with 1 indicating not important at all, and 10 indicating very important.

Confidence. Confidence in using MET on a 1-10 scale, with 1 indicating not confident, and 10 indicating very confident.

Readiness. Readiness to use MET on a 1-7 scale, with 1 indicating not ready, 4 indicating unsure, and 7 indicating ready.

These scales (Appendix 12) are a modified version of Rollnick et al's (1999) rating scales for evaluating a person's motivation to change. In the current study, the scales are used to measure the health practitioners' motivation to use MI. Broers et al (2005) used these scales similarly as a measure of GPs' confidence in using behaviour change counselling techniques (agenda setting, exploration of reasons for non-adherence, information exchange, readiness and confidence rulers, brain-storming) after training, and found a statistically significant improvement in GPs confidence in their own skills after training.

Additionally, the diabetes health practitioners were given a Motivational Interviewing Knowledge Test (MIKT) pre- and post-training. The MIKT was developed for the current study to assess the knowledge about MI acquired during training (Appendix 13).

Descriptive statistics of the results of each of these scales are reported, and inferential confidence intervals were used to evaluate statistical difference and equivalence between the pre- and post-training results.

Results

Treatment Integrity

Risk Factor Interview Checklist

The total scores derived from the independent ratings (total score) on the RFIC and MET were statistically different for PE and MET, with MET receiving higher ratings than PE (Table 31). This suggests that when the DNE performed MET, their interviewing style was more patient-centred than when they performed PE. This is consistent with MET being a patient-centred intervention.

Table 31. Independent ratings means, confidence intervals, and results of statistical tests

	Mean	95% CI	Different	Equivalent
<i>RFIC</i>				$\Delta = 6.853$
PE	6.444	4.7001–8.188		
MET	8.444	16.856–20.033	*	ns
<i>MET Audit</i>				$\Delta = 6.730$
PE	18.7782	16.092–20.864		
MET	29.889	27.995–31.783	*	ns
<i>Resistance</i>				$\Delta = 1.665$
PE	3.667	2.936–4.395		
MET	2.778	1.716–3.840	ns	ns
<i>Readiness</i>				$\Delta = 1.295$
PE	1.111	0.5378–1.6844		
MET	2.556	1.9412–3.1704	*	ns

$\Delta = 1$ standard deviation of PE and MET samples

*=statistically significant at .05 level

ns=not statistically significant at .05 level

On no items on the RFIC were PE and MET statistically equivalent (Table 31). On five items (i.e., Items 5, 7, 9, 10, and 11), however, PE and MET were statistically different (Table 32).

Table 32. RFIC item means, confidence intervals, and results of statistical tests

	Mean	95% CI	Different	Equivalent $\Delta = 0.883$
<i>Item 1: Style facilitated patient understanding and comfort</i>				
PE	1.667			
MET	2.000			
<i>Item 2: Explicit invitation to the patient to collaborate</i>				
PE	1.111	-0.941–0.316		
MET	0.333	-0.102–0.769	ns	ns
<i>Item 3: Inquired about the patients objective for the interview</i>				
PE	0.222	0.220–0.664		
MET	0.778	0.133–1.423	ns	ns
<i>Item 4: Opened questions to explore relevant issues</i>				
PE	0.667			
MET	2.000			
<i>Item 5: Occasional silence enabling the patient to reflect on issues related to lifestyle change</i>				
PE	0.556	0.091–1.021		
MET	1.778	1.496–2.059	*	ns
<i>Item 6: Periodic summary statements to clarify potential barriers or supports for change</i>				
PE	0.000			
MET	1.778			
<i>Item 7: Validated the patients feelings about health behaviours</i>				
PE	0.444	0.062–0.827		
MET	1.889	1.713–2.065	*	ns
<i>Item 8: Helped the patient view unsuccessful efforts to change as learning experience</i>				
PE	0.000			
MET	1.000			
<i>Item 9: Invited the patient to note issues that may not have been identified in the interview</i>				
PE	0.444	0.144–0.745		
MET	1.444	1.079–1.809	*	ns
<i>Item 10: Reviewed supports or barriers, and state change could be achieved in manageable steps</i>				
PE	0.556	0.282–0.829		
MET	1.333	0.966–1.700	*	ns
<i>Item 11: Expressed support for the patients freedom of choice</i>				
PE	0.222	-0.060–0.504		
MET	1.444	0.980–1.909	*	ns
<i>Item 12: Negotiated next step for counseling about change</i>				
PE	0.778	0.130–1.073		
MET	1.333	0.950–1.716	ns	ns
<i>Item 13: Verbally reinforced the patients efforts to discuss, prepare for, or initiate change</i>				
PE	0.778	0.416–1.140		
MET	1.333	0.957–1.710	ns	ns

$\Delta = 1$ standard deviation of item scores for PE and MET

*=statistically significant at .05 level

ns=not statistically significant at .05 level

The use of occasional silence so that the participant could reflect upon issues related to lifestyle change (Item 5) was fully demonstrated on all MET audiotapes. Yet, it was only partially, or not demonstrated, on all but one of PE audiotapes (Table 32). All, but one, of the MET audiotapes were rated as fully demonstrating the identification and validation of positive and negative feelings about health risk behaviours (Item 7). In contrast, this was either partially or not demonstrated on all but one PE audiotapes (Table 32). Before the end of the interview, an invitation to note personally relevant issues not identified in the interview was fully demonstrated on the majority (n=6) of MET audiotapes (Item 9). This was not demonstrated on the majority (n=6) of PE audiotapes (Table 32). The majority of MET audiotapes were rated as partially or fully demonstrating a review of supports and barriers, and a statement how change can be achieved in manageable steps (Item 10). This was rated as occurring only partially or not at all on PE audiotapes (Table 32). Similarly, there was partial or full expression of support for the participant's freedom to make an informed choice about whether to proceed with a plan for change (Item 11) on all, but one, of MET audiotapes. In contrast, this was either partially or not demonstrated on all PE audiotapes (Table 32).

Table 32. Frequency of responses on RFIC items

	Demonstrated		
	<i>Not at all</i>	<i>Partially</i>	<i>Fully</i>
<i>Item 1: Style facilitated patient understanding and comfort</i>			
PE	0	3	6
MET	0	0	9
<i>Item 2: Explicit invitation to the patient to collaborate</i>			
PE	1	8	0
MET	7	2	1
<i>Item 3: Inquired about the patients objective for the interview</i>			
PE	8	0	1
MET	5	1	3
<i>Item 4: Opened questions to explore relevant issues</i>			
PE	4	4	1
MET	0	0	9
<i>Item 5: Occasional silence enabling the patient to reflect on issues related to lifestyle change</i>			
PE	5	3	1
MET	0	2	7
<i>Item 6: Periodic summary statements to clarify potential barriers or supports for change</i>			
PE	9	0	0
MET	0	2	7
<i>Item 7: Periodic summary statements to clarify potential barriers or supports for change</i>			
PE	6	2	1
MET	0	1	8
<i>Item 8: Helped the patient view unsuccessful efforts to change as learning experience</i>			
PE	9	0	0
MET	3	3	3
<i>Item 9: Invited the patient to note issues that may not have been identified in the interview</i>			
PE	6	2	1
MET	2	1	6
<i>Item 10: Reviewed supports or barriers, and state change could be achieved in manageable steps</i>			
PE	4	5	0
MET	1	4	4
<i>Item 11: Expressed support for the patients freedom of choice</i>			
PE	7	2	0
MET	1	3	5
<i>Item 12: Negotiated next step for counseling about change</i>			
PE	3	5	1
MET	2	2	5
<i>Item 13: Verbally reinforced the patients efforts</i>			
PE	4	3	2
MET	2	2	5

Statistical tests for difference and equivalence were not possible on four items (i.e., Items 1, 4, 6, and 8) as the lack of variance for either the PE or MET ratings meant that correlations, and hence the inferential confidence interval for dependent samples, could not be calculated (Table 31). For example, all the MET audiotapes were rated as fully demonstrating a communication style that facilitated participant understanding and comfort (Item 1). While the majority (i.e., $n=6$) of PE audiotapes also fully demonstrated this, a third were rated as only partially demonstrating such a communication style (Table 32). The use of open-ended questions to explore relevant issues and facilitate the participant's involvement (Item 4) was fully demonstrated on all MET audiotapes. In contrast, this was demonstrated either only partially or not at all on all but one PE audiotapes (Table 32). All of the PE audiotapes were rated as not demonstrating periodic summary statements to clarify potential barriers or supports for change (Item 6). This, however, was demonstrated fully on all but two MET audiotapes (Table 32). Similarly, none of the PE audiotapes were rated as helping the participant view prior unsuccessful change efforts as important learning experiences (Item 8). In contrast, this was either partially, or fully, demonstrated on most ($n=6$) MET audiotapes (Table 32).

PE and MET scores were statistically indeterminate (i.e., neither statistically different nor equivalent) on four items (i.e., Items 2, 3, 12, and 13; Table 31). For example, the majority of PE and MET audiotapes were rated as not demonstrating an explicit invitation to collaborate in assessing readiness to begin or to continue lifestyle change at the beginning of the session (Item 2). One MET audiotape, however, was rated as fully demonstrating this (Table 32). Note, however, that the inter-rater reliability for this item was low, so these results should be treated with caution.

Similarly, most of the PE and MET audiotapes were rated as not inquiring about the participant's objectives at the beginning of the session (Item 3). This, however, was fully demonstrated on a third of the MET audiotapes (Table 32). Negotiation about the next step for counselling about change (Item 12) was fully demonstrated on five MET audiotapes, but was also not demonstrated on another two MET audiotapes. This was either partially or not demonstrated on all but one PE audiotapes (Table 32). Reinforcement of the participant's effort to discuss, prepare for, or initiate change (Item 13) was fully demonstrated on five MET audiotapes, but was also not demonstrated on two MET audiotapes. This was not demonstrated on four PE audiotapes, but was also fully demonstrated on another two PE audiotapes (Table 32).

MET Audit

The total scores given by the independent rater on the MET Audit were also statistically different for PE and MET, with MET receiving higher ratings than PE (Table 33). This suggests that the DNEs were using key MI skills during the MET sessions.

PE and MET were statistically different (Table 33) on half of the MET Audit items (i.e., Items 3, 4, 6, 7, and 10). For example, the majority of MET audiotapes were rated as eliciting self-motivational statements (Item 3) moderately to a lot, whereas self-motivational statements were not elicited on all but one of the PE audiotapes (Table 34).

Table 33. MET Audit item confidence intervals and results of statistical tests

	Mean	95% CI	Different	Equivalent $\Delta=1.379$
<i>Item 1: Session was actively directed by the therapist</i>				
PE	2.333	1.619–3.048		
MET	3.222	2.885–3.559	ns	ns
<i>Item 2: Session was focused by the therapist on the patient's diabetes</i>				
PE	3.222	2.686–3.759		
MET	3.778	3.534–4.021	ns	*
<i>Item 3: Therapist elicited self-motivational statements</i>				
PE	0.111	-0.067–0.289		
MET	2.383	1.871–2.796	*	ns
<i>Item 4: Therapist used summaries</i>				
PE	0.444	0.097–0.792		
MET	2.444	1.775–3.113	*	ns
<i>Item 5: Therapist praised or affirmed the patient</i>				
PE	1.889	1.592–2.186		
MET	2.333	1.453–2.714	ns	*
<i>Item 6: Therapist gave advice, direction or education to the patient</i>				
PE	1.111	0.359–1.863		
MET	2.444	1.922–2.967	*	ns
<i>Item 7: Therapist used reflective listening</i>				
PE	1.111	0.789–1.433		
MET	2.778	2.434–3.121	*	ns
<i>Item 8: Therapist used dynamic interpretations</i>				
PE	4.000			
MET	4.000			
<i>Item 9: Therapist actively explored non-diabetes issues</i>				
PE	3.000			
MET	4.000			
<i>Item 10: Therapist style was empathic</i>				
PE	1.556	1.190–1.923		
MET	2.556	1.983–3.129	*	ns

$\Delta=1$ standard deviation of item scores for PE + MET

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Table 34. Frequency of responses on MET Audit items

	Rating				
	<i>Not at all</i>	<i>A little</i>	<i>Moderately</i>	<i>A lot</i>	<i>Extremely</i>
<i>Item 1: Session was actively directed by the therapist</i>					
PE	0	4	1	1	3
MET	0	0	1	5	3
<i>Item 2: Session was focused by the therapist on the patient's diabetes</i>					
PE	0	0	4	1	5
MET	0	0	0	2	7
<i>Item 3: Therapist elicited self-motivational statements</i>					
PE	8	1	0	0	0
MET	0	2	1	6	0
<i>Item 4: Therapist used summaries</i>					
PE	5	4	0	0	0
MET	0	2	2	4	1
<i>Item 5: Therapist praised or affirmed the patient</i>					
PE	0	3	4	2	0
MET	0	1	6	0	2
<i>Item 6: Therapist gave advice, direction or education to the patient</i>					
PE	0	2	1	2	4
MET	0	6	2	1	0
<i>Item 7: Therapist used reflective listening</i>					
PE	2	4	3	0	0
MET	0	0	4	3	2
<i>Item 8: Therapist used dynamic interpretations</i>					
PE	9	0	0	0	0
MET	9	0	0	0	0
<i>Item 9: Therapist actively explored non-diabetes issues</i>					
PE	0	2	1	1	5
MET	0	0	0	0	9
<i>Item 10: Therapist style was empathic</i>					
PE	0	5	2	3	0
MET	0	2	2	3	2

Summaries (Item 4) were either not used or used only a little on all PE audiotapes. In contrast, summaries were used on all MET audiotapes, and were used a lot or extremely on five of these (Table 34). Advice, direction or education was given (Item 6) during both PE and MET. This, however, was rated as being provided a lot or extremely on the majority (i.e. n=6) of PE audiotapes, but only a little or not at all on the majority (i.e., n=6) of MET audiotapes (Table 34). Similarly, reflective listening (Item 7) was rated as occurring a lot to extremely on five of the MET audiotapes (Table 34). It, however, was rated as not occurring or occurring only a little on the majority (i.e., n=6) of PE audiotapes.

While the DNEs style was rated as empathic (Item 10) during both interventions, the style was more empathic during MET than PE (Table 34). On five MET audiotapes the DNEs were rated as a lot to extremely empathic, whereas they were rated as only a little empathic on five PE audiotapes.

PE and MET, however, were statistically equivalent (Table 33) on two MET Audit items (i.e., Items 2 and 5). Both interventions were rated as focusing on the participant's diabetes (Item 2), with all the MET, and the majority (i.e. n=6) of PE, audiotapes rated as doing this a lot or extremely (Table 34).

Praise and affirmation (Item 5) were used similarly during PE and MET. While praise and affirmation was rated as occurring extremely on two MET audiotapes, it was rated as occurring moderately for the majority (i.e., n=6) of MET audiotapes, and a little to a lot for all PE audiotapes (Table 34).

Statistical tests for difference and equivalence were not possible for two items (i.e., Items 8 and 9) as the lack of variance meant that correlations, and hence the inferential confidence interval for dependent samples, could not be calculated (Table 33). There was no difference between PE and MET on Item 8 as dynamic interpretations did not occur during either intervention (Table 34).

Non-diabetes issues (Item 9) were never actively explored during MET. These, however, were explored (a little to a lot) on four PE audiotapes (Table 34). Note, however, that the inter-rater reliability was low for this item, so these results should be treated with caution. Lastly, PE and MET were statistically indeterminate (i.e., neither statistically different nor equivalent) on Item 1 (Table 33). The session was actively directed by the DNE moderately to extremely on all MET audiotapes, and on five PE audiotapes (Table 34).

Therapy Process

Resistance and readiness for change

Resistance behaviour in the form of arguing was not observed on any MET audiotape, but was observed on PE audiotapes (Table 35). The arguing, which involved challenging (i.e., the participant directly challenged the accuracy of what the DNE said), was observed on five PE audiotapes. Arguing in the form of discounting and hostility was not observed on either the PE or MET audiotapes.

Table 35. Number of sessions in which signs of resistance was observed

Signs of resistance	PE	MET
<i>Arguing</i>		
Challenging	5	0
Discounting	0	0
Hostility	0	0
<i>Interrupting</i>		
Talking over	6	0
Cutting off	0	0
<i>Denying</i>		
Blaming	2	2
Disagreeing	2	2
Excusing	6	8
Claiming impunity	0	0
Minimising	1	1
Pessimism	5	5
<i>Ignoring</i>		
Inattention	1	0
Non-answer	1	0
No response	0	0
Side-tracking	2	1

Similarly, resistance behaviour in the form of interrupting was not observed on any MET audiotapes, but was observed on PE audiotapes (Table 35), with interrupting by talking over (i.e., the participant spoke while the DNE was still

talking, without waiting for an appropriate pause or silence) occurring on the majority (n=6) of the PE audiotapes. Interrupting in the form of cutting off (i.e., the participant breaking in with words obviously intended to cut the DNE off, e.g., “now wait a minute”, “I’ve heard enough”) was not observed on either the PE or MET audiotapes.

Resistance behaviour in the form of denying, however, was observed, and for a similar number, on both PE and MET audiotapes (Table 35). Excusing and pessimism were observed the most (i.e., n=5) on PE and MET audiotapes, with blaming, disagreeing, and minimising occurring on only one or two audiotapes from both interventions. Denying in the form of claiming impunity (i.e., the participant claiming that s/he was not in danger from diabetes) was not observed on either the PE or MET audiotapes.

Resistance behaviour in the form of ignoring was observed during both interventions (Table 35). Ignoring, which involved sidetracking (i.e. the participant changing the direction of the conversation that the DNE had been pursuing), however, was observed on only one MET audiotape. In contrast, ignoring, which took the form of sidetracking, inattention (i.e., the participant’s response indicated that s/he had not been following or attending to the DNE) and a non-answer (i.e., the participant gave no audible reply to the DNE’s query), was observed on four PE audiotapes.

Signs of readiness for change were observed during both interventions (Table 36). Self-motivational statements, envisioning (i.e., the participant begins to talk about how life might be after a change, to anticipate difficulties if a change were made, or to discuss advantages of change), and experimenting (i.e., the participant reported they had begun experimenting with possible change approaches between

sessions) were observed on the majority (n=6) of MET audiotapes. In contrast, self-motivational statements and experimenting were observed less frequently (i.e., n=3) on PE audiotapes, and envisioning was not observed on any PE audiotape.

Table 36. Number of sessions in which signs of readiness for change were observed

Signs of readiness to change	PE	MET
Decreased resistance	0	0
Decreased questions about the problem	0	0
Resolve	1	1
Self-motivational statements	3	8
More questions about change	3	0
Envisioning	0	7
Experimenting	3	7

Increased questions about change were observed (i.e., n=3) on PE audiotapes, but on none of the MET audiotapes. Signs of readiness for change in the form of decreased resistance (i.e., the participant stops arguing, interrupting, denying, or objecting) and decreased questions about the problem were not observed on any PE or MET audiotape, and resolve (i.e. the participant appears to have reached a resolution, and may seem more peaceful, relaxed, calm, unburdened, or settled) was observed on only one audiotape from each intervention.

MISC behaviour counts

Therapist behaviour. Analysis of the transcripts shows that during PE there were 0.31 reflections to a question, whereas for MET the ratio of reflections to questions was higher at 1.17 reflections to a question. Additionally, during MET sessions there were more open questions, complex reflections (paraphrasing and summarising), and MI-consistent responses than during PE (Figure 39).

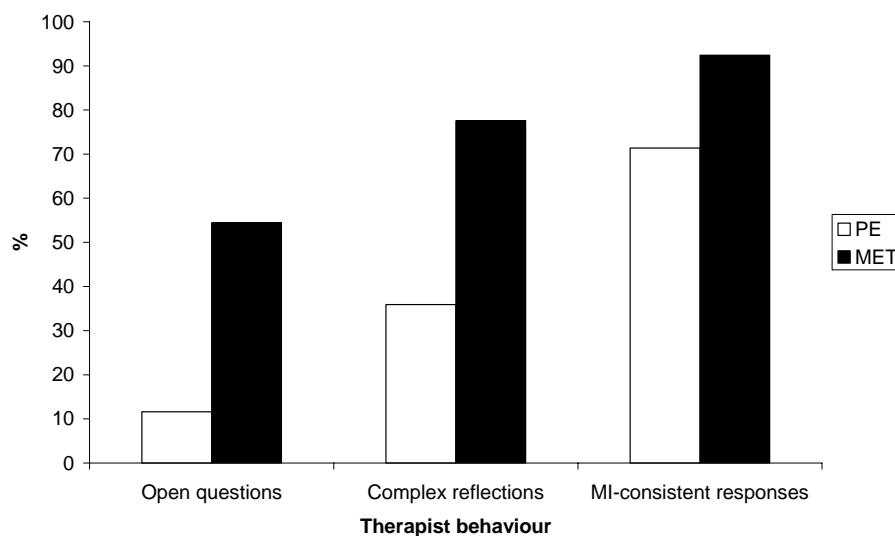


Figure 39. DNE use of key MI responses during PE and MET

The DNE's behaviour was statistically different for four of the six MI-consistent responses (Table 37), with the DNEs providing advice with permission, emphasising control, and using open questions and reflections more during MET compared to during PE. There was also a statistically significant difference on two of the five MI-inconsistent responses, with the DNEs providing advice without permission and directing or ordering the patient more during PE compared to during MET (Table 37).

Table 37. MISC means (per minute), inferential confidence intervals, and results of statistical tests –
MICO and MIN responses during PE vs MET

Therapist Behaviour	Mean	95% CI	Different	Equivalent
<u>MI-consistent responses</u>				
<i>Advice with permission</i>				$\Delta=.080$
PE	.112	.067–.156		
MET	.026	.017–.036	*	ns
<i>Affirmation</i>				$\Delta=.252$
PE	.375	.256–.494		
MET	.219	.177–.260	ns	ns
<i>Emphasize control</i>				$\Delta=.060$
PE	.022	.011–.033		
MET	.080	.059–.102	*	ns
<i>Open questions</i>				$\Delta=.341$
PE	.267	.189–.344		
MET	.726	.629–.823	*	ns
<i>Reflections – total</i>				$\Delta=.740$
PE	.661	.410–.909		
MET	1.321	1.136–1.505	*	ns
<i>Reframe</i>				$\Delta=.040$
PE	.020	.004–.035		
MET	.342	.023–.045	ns	ns
<i>Support</i>				$\Delta=.138$
PE	.169	.104–.235		
MET	.086	.062–.111	ns	ns
<u>MI-inconsistent responses</u>				
<i>Advice without permission</i>				$\Delta=.218$
PE	.281	.165–.396		
MET	.106	.070–.142	*	ns
<i>Confront</i>				$\Delta=.082$
PE	.047	.025–.069		
MET	.030	.001–.060	ns	*
<i>Direct</i>				$\Delta=.185$
PE	.256	.160–.352		
MET	.054	.025–.084	*	ns
<i>Raise concern – without permission</i>				$\Delta=.045$
PE	.006	.002–.013		
MET	.031	.007–.050	ns	ns
<i>Warn</i>				$\Delta=.016$
PE	.007	-.002–.015		
MET	.003	.000–.005	ns	*

Client behaviour. During MET there was a greater percent of change talk overall (Figure 40). Additionally, when the pattern of change talk was examined across session time, there was more change talk in each third of MET compared to PE, and the percent of change talk was highest in the last third of MET, whereas there was a decline in change talk in the last third of PE.

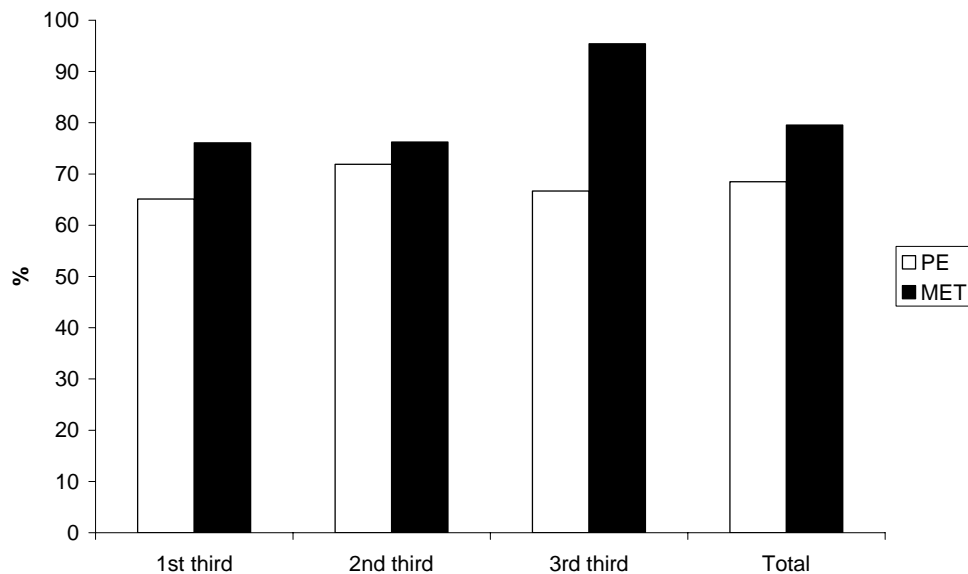


Figure 40. Percent change talk during PE and MET sessions

Collaboration

Collaboration was low during PE. For both DNEs agreement on the goals for change was 50% or less for all PE sessions, but one (in which 100% agreement was obtained; Figure 41). Collaboration was higher during MET, with between 50-100% agreement on all sessions but two, and 100% agreement on more than 50% of sessions for both DNEs.

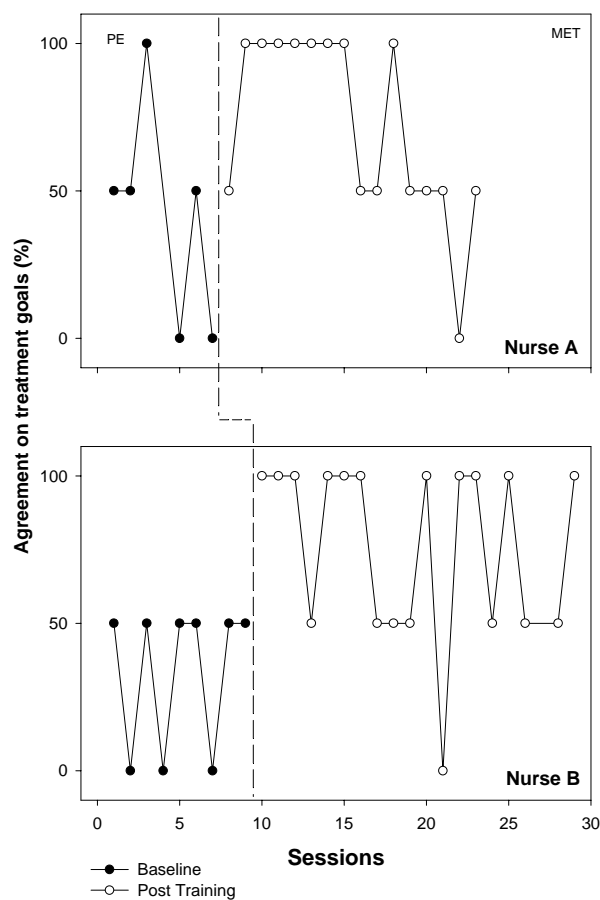


Figure 41. Collaboration between DNE and participants

Training

Trainees' Ratings and Knowledge

Importance. Prior to training some of the health practitioners were uncertain how important MET was for enhancing diabetes self-management (i.e. ratings ranged from 4-10 on the 1-10 scale, with 1=not very important, and 10=very important). As a group, however, they considered that MET was important (Table 38). Post-training results were statistically equivalent to pre-training (Table 38), but the range of scores narrowed (i.e. range of 8-10). This suggests that the health practitioners continued to

consider MET important for improved diabetes self-management, but that those who were uncertain about the importance of MET prior to training shifted to considering MET as important post-training.

Table 38. Confidence intervals and results of statistical tests - Importance, confidence, readiness, and knowledge

Scale	Mean	95% CI	Different	Equivalent
Importance (1-10)				$\Delta = 1.97$
Pre-training	8.308	7.411–9.205	ns	*
Post-training	8.769	8.348–9.190		
Confidence (1-10)				$\Delta = 1.81$
Pre-training	2.806	2.073–3.619	*	ns
Post-training	5.000	4.186–5.814		
Readiness (1-7)				$\Delta = 1.79$
Pre-training	4.231	3.465–4.996	ns	ns
Post-training	5.192	4.535–5.850		
Knowledge (%)				$\Delta = 8.42$
Pre-training	10.000	6.211–13.789	*	ns
Post-training	53.077	45.524–60.630		

$\Delta = 1$ standard deviation of PE and MET samples

*=statistically significant at .05 level

ns=not statistically significant at .05 level

Confidence. Pre-training the diabetes health workers had little confidence in using MET. While still not high, post-training confidence in using MET increased, such that the pre- and post training scores were statistically different (Table 38).

Readiness. As a group the diabetes health workers were unsure as to whether they were ready to use MET at baseline. This uncertainty, although still present post-training, appears to have reduced (Table 38), with the pre- and post-training scores not statistically equivalent, but the difference was not large enough to reach statistical significance.

MI knowledge test

Pre-training results suggest that the diabetes health workers' knowledge about MI was low. Post-training, however, their knowledge showed a marked increase such that, while their knowledge about MI as a group could still not be considered high post-training, the pre- and post-training scores were statistically different (Table 38). This suggests that they gained an increased understanding of MI as a result of the training.

Training plus supervised practice and feedback (DNE performance only)

Percent open questions. After MI training, the percent of open questions used by Nurse A achieved beginning proficiency in 75% of sessions (Figure 42), reaching competence in one session (session two). In contrast, the percent of open questions used by Nurse B was low (mostly below beginning proficiency) initially, but increased with supervised practice and feedback, such that the percent open questions was mostly (i.e., 71% of sessions) above beginning proficiency from session seven onwards (Figure 42), reaching competence in session 19.

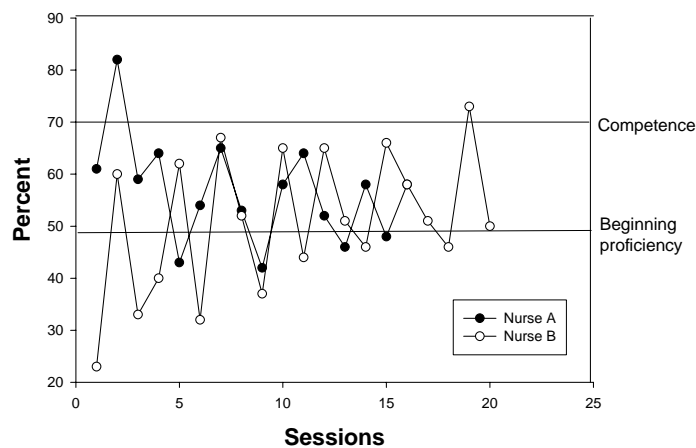


Figure 42. Percent open questions post-training (MET)

Both nurses did not consistently reach beginning proficiency for the ratio of reflections to questions in the initial (i.e., first four sessions) sessions post-training (Figure 43). Yet, with supervised practice and feedback, the ratio of reflections to questions for Nurse B was above beginning proficiency from session four onwards, reaching competency in 25% of sessions. Nurse A, however, took longer to achieve beginning proficiency for the ratio of reflections to questions, with this criteria being met on all but one session from session nine onwards, and reaching competence in the last session (session 16).

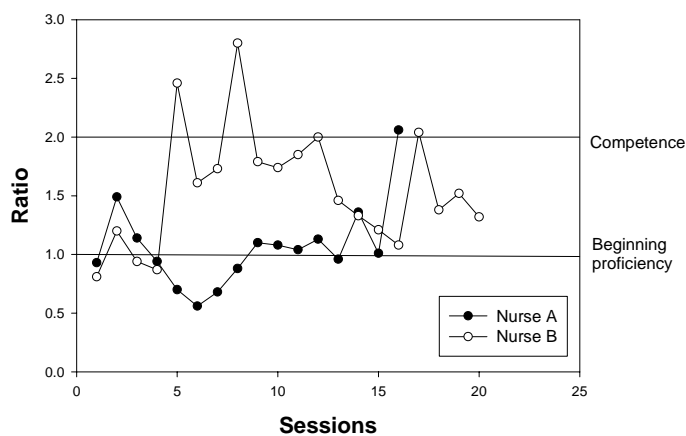


Figure 43. Ratio of reflections to questions post-training (MET)

Both nurses, however, achieved competence in the percent of complex reflections immediately post-training (Figure 44), with the exception of two earlier sessions (session five and six) in which Nurse A did not achieve beginning proficiency. Furthermore, both nurses appear to have maintained this over time, with an upwards trend in the percent complex reflections over time for both of them.

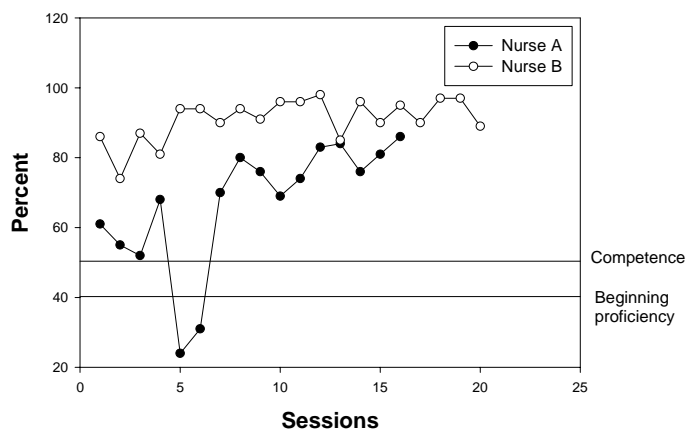


Figure 44. Percent of complex reflections post-training (MET)

Similarly, both nurses achieved beginning proficiency for the percent of MI-consistent responses immediately post-training (Figure 45), with 67% and 75% of sessions in which this was achieved by Nurse A and B, respectively. Competence, however, was achieved in only one session (session 12 by Nurse B).

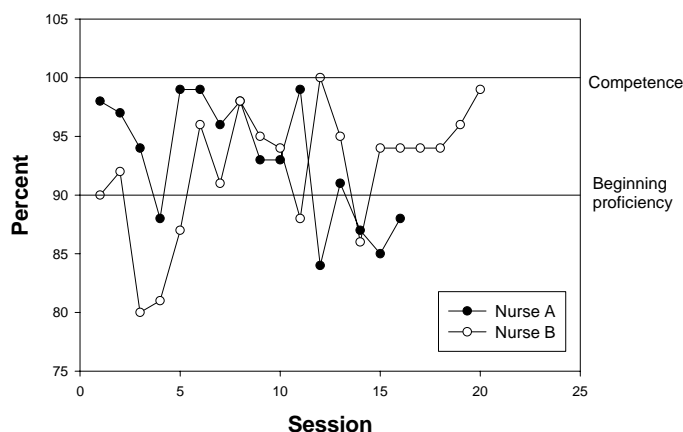


Figure 45. Percent on MI-consistent response post-training (MET)

Discussion

The statistically significant differences between PE and MET total scores on the RIFC and the MET Audit suggest that the DNEs' behaviour during PE and MET were qualitatively different. This is consistent with the findings of Study 1 and 2 in which the independent rater, blind to condition, correctly identified 94% and 100% of sessions respectively, suggesting that PE and MET were qualitatively and distinguishably different interventions.

The higher ratings that MET received on the RIFC are evidence that the DNEs were being more patient-centred (Hypothesis 1). Specifically, during MET (in contrast to PE) the DNEs allowed occasional silence so that the participant could reflect upon issues related to lifestyle change; used periodic summary statements to clarify potential barriers or supports for change; identified and validated the participant's positive and negative feelings about health risk behaviours; and tended to help the participant view prior unsuccessful efforts to change as important learning experiences. Then, before ending the interview, they invited the participant to note personally relevant issues that may not have been identified during the interview; reviewed supports and barriers, and stated how change could be achieved in manageable steps; and expressed support for the participant's freedom to make an informed choice about whether to proceed with a plan for change at that time.

Consistent with the MET sessions being more patient-centred, there also appears to have been greater collaboration between the participants and the DNEs during MET compared to PE (Hypothesis 2). Furthermore, the higher ratings MET

received on the MET Audit, compared to PE, suggest that the DNEs were not just being more patient-centred, but were also behaving in a way that was consistent with MI (Hypothesis 3). In particular, they elicited self-motivational statements, used summaries and reflective listening, and were more empathic than during PE. These are all key MI skills (Miller & Rollnick, 2002, 1991).

While advice, direction or education were provided during both interventions, this occurred less frequently during MET compared to PE. This again lends support to the integrity of the interventions as the provision of education is a primary goal of PE. In contrast, the provision of advice, direction or education is not the focus of MET. Instead, advice, direction or education may be given in MET, but when the participant is ready to receive it (i.e., with consideration of their readiness for change) and in small doses (Miller & Rollnick, 2002; 1991).

During the MET sessions, the DNEs' behaviour was also consistent with MI, as measured by the MISC. There was a three-fold increase in the ratio of reflections to questions during MET. They also used more open questions (Hypothesis 3a), complex reflections (Hypothesis 3b) and MI-consistent responses (Hypothesis 3c) during MET compared to PE. Furthermore, the ratio of reflections to questions and the percent open questions satisfied criteria for beginning proficiency in MI, and the percent complex reflections and MI consistent responses reached criteria for competent MI (Moyers, Martin, Manuel & Miller, 2005).

Furthermore, these changes in the DNE behaviour appear to have led to changes in the participants' behaviour consistent with MI theory (Hypothesis 4). Participants during MET engaged in more change talk than participants during PE (Hypothesis 4a). Additionally, MET participants engaged in more change talk towards the end of the sessions. This latter finding is particularly significant as Amrhein et al (2003) found that client speech toward the end of session was the strongest predictor of behaviour change.

Additionally, PE appears to have elicited active resistance in the form of arguing (challenging), interrupting (talking over), and ignoring (side-tracking), whereas these behaviours were not observed on the MET audiotapes (Hypothesis 4b). This is consistent with Patterson and Forgatch's (1985) research which found that education elicited resistance, and is also consistent with MI's goal of avoiding eliciting resistance.

Resistance in the form of excusing or pessimism was observed similarly on both the PE and MET audiotapes. This suggests that both groups of participants were similar with regards to their unwillingness to accept responsibility for their behaviour and their belief in the possibility of change, and therefore were likely to be equally difficult to engage in behaviour change. That this type of resistance behaviour was observed on the MET audiotapes is not unexpected as part of the focus of MI is to openly explore barriers to change. The primary focus of MET, however, is to elicit self-motivational statements. Consistent with this, self-motivational statements, envisioning and experimenting were observed on all but one of the MET audiotapes, but on only three PE audiotapes.

While, in general, the health practitioners considered MET an important intervention to enhance diabetes self-management pre- and post-training, individuals who were uncertain about the usefulness of MET pre-training considered it important after training (Hypothesis 5). Thus their uncertainty may have been due to a lack of knowledge or understanding about what MET involved, so that once they had gained a better understanding of MET, they too considered it an important intervention to enhance diabetes self-management.

Training increased the practitioners' knowledge of MI (Hypothesis 6) and their confidence in using MET (Hypothesis 7). This statistically significant increase in confidence is similar to that achieved by Broers et al (2005) who provided two 4.5 hour training sessions for GPs on behaviour change counselling, which included MI techniques. Despite the statistically significant increase in confidence in the current study, the health practitioners' confidence in using MI after the two days training was still low (i.e. mean of 5 out of 10, with 1 being not confident at all, and 10 being very confident). Doherty et al (2000) report a similar finding, stating that, after a training programme in behaviour change counselling (which included MI) for diabetes health professionals, comprising monthly one hour workshops, fortnightly one hour individual supervision, and monthly one hour peer supervision over a six month period, 'the perception of incompetence, came up repeatedly' and that 'six of the nine respondents reported that they were not very confident in their ability to facilitate behaviour change' (p.268). This suggests the importance of post-training supervised practice, which includes feedback on actual practice.

It should be noted, however, that the level of confidence in using MI in the current study appears higher after two days training than that reported by Doughty et al (2000). Several factors may have contributed to these differing results. The workshop based training in the current study was more intensive (i.e, twelve hours over two consecutive days versus one hour per month for six months), which may have allowed for greater skill development and consolidation. While Doherty et al (2000) only have the practitioners self-report of their skill level post-training, rather than actual measure of their skill in clinical practice, their results suggest that the majority of the practitioners reported using 'basic consultation skills', such as patient-centred summaries, but 'fewer had acquired or used more complex competencies' (p.268) and included MI in a list of topics about which they wished to receive more training.

Additionally, while Doherty et al (2000) report that they utilised 'adult education models' (p.265) in their training, the greater time available for the initial training workshop in the current study, meant that more time would have been available for the training to have been conducted consistent with Knowles (1973) theory of adult education. Thus, it is likely that the trainers in the current study would have had more opportunity to act as a facilitator (Rogers, 1969) drawing knowledge and skill out of the trainees, and to pay more attention to the trainees' readiness to learn. The training in the current study was also solely focused on MI, with the trainers modelling the spirit and practice of MI throughout the training.

Despite the increase in confidence in using MET in the current study, as a group, the health practitioners, however, were still feeling unsure as to whether they were ready to use MET post-training (Hypothesis 8). Doherty et al (2000) also found that, despite their training programme, which included post-training individual and peer supervision, the diabetes professionals in their study also considered that they needed more time to develop the necessary skills for practice. The findings of both these studies further suggest the importance of supervised practice post-training.

Additionally, research suggests that upwards shifts in readiness are associated with shifts in the perceived importance of change (Rollnick, Morgan & Heather, 1996). If these results can be generalised to the case of the health practitioners in the current study, it would be expected that their readiness to use MET would be higher given that they considered MI important for enhancing diabetes self-management. Since their baseline ratings of importance were already high, however, it may be that increased confidence (and knowledge), through further training or ongoing support (i.e., supervised practice), would increase their readiness to use MET.

Furthermore, there may be other barriers which were limiting their readiness to use MET. Doherty et al (2000), for example, identified that “organisational issues such as balancing other commitments, covering for absent colleagues at short notice, managing overbooked clinics and concerns that longer consultations might result in longer waiting times” (p.268) as barriers to the implementation of behaviour change counselling in diabetes. Future research needs to explore if these perceived barriers do exist and develop ways of overcoming or minimising any such barriers.

Yet, the current study provides evidence that, with supervised practice, the DNE's were able to develop and practice MI skills to the level of at least beginning proficiency up to 12 months post-training. This finding is again similar to that of Doherty et al (2000) who found that, while diabetes practitioners 'found it difficult to resist informing or advising people rather than eliciting thoughts, feelings and patient generated plans' (p.275), many were able to acquire change counselling skills by six months with training plus supervised practice.

The findings of the current study are also consistent with Miller et al's (2004) research on MI training, which suggests that post-training supervision (feedback and/or coaching) was necessary for significant and sustained (up to eight months post-training) changes in practitioners' behaviour. Additionally, the current study found evidence of client within session behaviour (e.g., increased change talk) up to 12 months post-training consistent with MI theory (Miller & Rollnick, 2002), which Miller et al (2004) also found, but only when training was combined with supervised practice.

The results for the DNEs in the current study, however, should be treated with caution as the DNEs were self-selected. They volunteered to be involved in the research, knowing that it would involve learning MI and the expectation that post-training they would utilise MI in their clinical practice, which would be audio-taped. It is therefore likely that they were motivated to learn MI and were willing to adapt their clinical practice. The same results may not be achieved with health professionals who are less motivated to learn new skills and apply these in their clinical practice.

Conclusions

Diabetes is a chronic illness that requires ongoing medical care and patient self-management to prevent acute complications and to reduce the risk of long-term complications (American Diabetes Association - ADA, 2003). In their guidelines for standards of care for people with diabetes the ADA (2003) recommended that all persons with diabetes attain and maintain recommended metabolic outcomes, including glucose and HbA1c levels; LDL cholesterol, HDL cholesterol, and triglyceride levels; blood pressure; and body weight. They further recommend that all persons with diabetes improve health through healthy food choices and physical activity. Thus, diabetes care is complex and requires that many issues, beyond glycaemic control, be addressed.

In order to achieve this, the ADA (2003) recommends that a diabetes management plan be formulated as an “individualised therapeutic alliance” (p.35) between the patient and his or her health practitioner(s), so that the individual with diabetes assumes an active role in his or her own diabetes care. Thus, they suggest that patient self-management be emphasised; the plan emphasise the involvement of the patient in problem solving as much as possible; each aspect of the management plan is understood and agreed on by the patient and the health practitioner(s); and the goals and treatment plan are reasonable. They also suggest that consideration be given to the individual’s personal and cultural preferences and lifestyle, and wishes and willingness to change.

The ADA (2003) does not suggest any particular interventions by which the above recommendations might be met. While PE continues to be the standard intervention for diabetes self-management, over the last 10-15 years, PE approaches to diabetes have developed to include patient empowerment, participation and collaboration (Norris et al., 2002). The present research included an evaluation of PE in routine clinical care, which was provided within a patient participation and collaboration context, and also included behavioural counselling techniques, such as setting small achievable goals in routine clinical care, producing mixed results concerning the effectiveness of PE.

The results of Study 1 suggest that there was no statistically significant difference in blood glucose following PE, although moderate ($d=.62$ post-PE) to large ($d=.84$ at 6-month follow-up) effect sizes were obtained. Taken together, this suggests that while there appears to have been an effect, it is not possible to draw conclusions regarding whether PE produced the effect. There was, however, a statistically significant decrease in triglycerides post-PE and at 12-month follow-up, again with moderate ($d=.58$, at 12-month follow-up) to large ($d=.88$ post-PE) effect sizes, suggesting that PE may have contributed to an improvement in this aspect of metabolic control. The mechanism(s) by which this change was achieved, however, is unclear as there was a lack of evidence supporting PE as a means of promoting changes in diabetes self-management behaviour, with mixed results for PE, and there was no evidence of improved diabetes knowledge following PE. There was, however, a statistically significant improvement in the PE participants emotional adjustment to diabetes, with a large effect size ($d=.84$) 12-months after PE.

MI appears to have potential as an alternative means of facilitating the APA's (2003) recommendations for the diabetes management plan particularly for those individuals with diabetes who know what is required in terms of diabetes self-management, but struggle with implementing and maintaining the necessary behaviour change. MI provides a means of developing a collaborative relationship between the individual with diabetes and his or her health practitioner, which includes an exploration of the individual's beliefs about diabetes, and the importance of behaviour change and metabolic control. Additionally, MI provides a means of working with individuals who might otherwise seem unwilling to change.

Indeed, Study 1 provides preliminary/tentative evidence that MI in the form of MET may be an effective intervention to improve diabetes outcome. In Study 1, the mean decrease in HbA1c over the 12-month period after MET was .67%. This is higher than the mean decrease (-.43%) in HbA1c reported in a recent meta-analysis of education and behavioural interventions for Type 2 diabetes (Gary et al., 2003). Additionally, the greatest improvement in blood glucose (i.e., -1.25% in HbA1c) occurred 6-months post-MET, whereas a recent meta-analysis of research on self-management education for Type 2 diabetes found that the decrease in HbA1c tended to have been lost by 4-months follow-up (Norris et al., 2002). Furthermore, the magnitude of this decrease in blood glucose was both statistically and clinically significant, with a large effect size ($d=-1.0$), and at a level consistent with that achieved in the DCCT and UKPDS, which was shown to decrease the risk of diabetes-related complications (DCCT Group, 1993; Turner, et al., 1996; UKPDS Group, 1998).

While there was no statistically significant decrease in blood glucose with PE, the mean decrease in HbA1c in the present research was -.70% which is also larger than that reported by Gary et al (2003) in their meta-analysis of education and behavioural interventions for Type 2 diabetes. Additionally, the effect for PE in the present research was greatest (i.e., mean decrease in HbA1c of -1.28%) 6-months post-intervention, which is a longer effect than that found by Norris et al's (2002) in their meta-analysis of self-management education for Type 2 diabetes. In contrast to MET, any effects of PE in the present research, however, were lost by 12-month follow-up.

The mean reduction in HbA1c after MET of .67% over 12 months also compares favourably with that reported in recent meta-analyses of psychological interventions (mostly comprising CBT) with Type 1 and Type 2 diabetes (Ismail et al., 2004; Winkley et al., 2006). Ismail et al (2004), for example, report a mean decrease in HbA1c of .76% for psychological interventions for Type 2 diabetes, while Winkley et al (2006) report only a small (.22%) decrease in HbA1c for adults with Type 1 diabetes following psychological intervention. The decrease in HbA1c of 1.25% at 6-month follow-up in the present research is also comparable to the decrease (mean of 1.2%) in HbA1c obtained in other studies of MI with diabetes (Smith et al., 1997; Viner et al., 2003; Channon et al., 2007).

The results of the present research are more notable given that in these studies the MI and psychological interventions were typically much longer (i.e., mean MI of 4.7 session, but up to 16 sessions, for up to 6-months, and a mean of 11 sessions for the psychological interventions) than the four sessions of MET provided in the present

research. Additionally, the psychological interventions and MI were typically provided by specialist interventionists, such as psychologists, whereas the MET in the present research was provided by usual clinical staff.

Even though the numbers in the present studies were small, statistically significant differences were found when group data were analysed, however. In particular, MET participants had statistically significant decreases in diabetes outcome measures which are considered markers of an individual's diabetes status and risk of experiencing complications from diabetes, with a statistically significant decrease in HbA1c at 6-month follow-up, and total cholesterol and LDL cholesterol at 12-month follow-up.

The MET participants also had a statistically significant decrease in the beliefs about the seriousness of diabetes post-intervention, with a moderate effect size ($d=.62$). These results are similar to that of Knight et al (2006) who found shifts in illness perceptions following intervention comprising MI and externalising conversations for adolescents with Type 1 diabetes, such that they were 'the consequences of diabetes were seen as having a less restrictive influence on their lifestyle than previously' (p.149). In the present research, the decrease in concern about the seriousness of diabetes after MET may have arisen from the participants successful attempts to change their diabetes self-management, leading them to be less concerned about the current seriousness of their diabetes, future complications, and the effect on their life. Further research exploring these findings is recommended.

The above findings suggest that MET may be more cost-effective than intensive, specialist-based psychological interventions. Additionally, the present research provides evidence that MI in the form of MET may be amenable to wider scale application, with usual clinical staff able to provide the intervention. This, however, contrasts with the findings of two previous studies (Clark et al., 2004; Rubak, 2005) evaluating the effectiveness of MI as an intervention for diabetes provided by usual clinical staff, which found no statistically significant decreases in HbA1c. The reason for this difference in findings is unclear, but may be a function of the MI training provided, as well as how MI was actually implemented, and the type of patients involved in the research. Ongoing supervision of MI practice, for example, was not provided as part of the training package in either of these other studies. Additionally, there is evidence that the practitioners providing the MI intervention in both these studies tended to be technique focused, rather than focussing on the core skills and spirit of MI, which was emphasised in the present research. Also, the present research targeted individuals who had been diagnosed with diabetes for some time (at least 12 months), and who had been identified as struggling with diabetes self-management. It may, therefore, be that MI was more relevant to the participants in the present research, as they could be considered as less motivated for, or more ambivalent about, engaging in the necessary diabetes self-management behaviours, whereas this was not the case in either of the other studies. The participants in Rubak's (2005) study, for example, were individuals newly diagnosed with Type 2 diabetes. Motivation may not be as great an issue in the initial stages post-diagnosis, but may become more of an issue after the individual with diabetes has had more experience with the difficulties of maintaining the

necessary behaviour changes required for diabetes self-management. It is recommended that future research explores when MI is most relevant and effective.

This finding that MET was similarly effective as longer psychological interventions is consistent with wider research on MI, which has typically found MI to be as effective as other credible treatments (Burke et al., 2002, 2003, 2004). In Project MATCH, for example, four sessions of MET was found to be as effective as 12 sessions of CBT for alcohol dependence (Project MATCH Research Group, 1993, 1997). Rubak et al's (2005) meta-analysis of MI with disease also found that the longer the follow-up the increased likelihood of finding an effect for MI. This too appears to have bourn out in the present research, with the greatest effect at 6-month, rather than immediately post-intervention or at 3-month follow-up.

In contrast to Rubak et al's (2005) finding of only a small, non-clinically significant effect for MI on cholesterol, both interventions in the present research appear to have led to statistically (and clinically) significant improvements in cholesterol. Following PE there was a statistically significant decrease in triglycerides, with a large effect size ($d=-.89$) post-intervention and a moderate effect size ($d=-.58$) at 12-month follow-up, whereas following MET there was a statistically significant decrease in both total cholesterol and LDL cholesterol at 12-month follow-up, with large effect sizes ($d=-.81$ and $d=-.79$, respectively). These results suggest that both interventions may have contributed to a decrease risk of macro-vascular complications associated with diabetes, but perhaps more so for MET (i.e., large, sustained effect over the 12-month follow-up).

Additionally, Studies 1-2 provide evidence of the process of change, with changes in self-management behaviour (particularly SMOBG in Study 1 and dietary compliance in Study 2) with MET consistent with improved blood glucose and cholesterol. Note, however, that SMOBG in itself would not be expected to produce changes in the metabolic data. This suggests that the MET participants altered other aspects of their diabetes self-management (e.g., diet, exercise, medication) as a function of the information provided from SMOBG.

Similarly, while the data did not support PE in terms of improved diabetes self-management, there was evidence of improved metabolic data. This suggests that they may have altered some other aspect(s) of their diabetes self-management, other than that selected as the target for change. This also leads to another important process finding in the present research – there appears to have been greater agreement between the practitioners and the participants in terms of the target behaviour for change with MET compared to PE. Additionally, the targets for change selected by the participants during MET tended to be consistent with the specialisation of the practitioner. SMOBG was the most frequent target for change when MET was provided by the DNEs (Study 1), and dietary compliance was the most frequent target for change when the dietitians provided MET (Study 2).

Study 3 provides evidence that a minimum of two days (12 hours) training was required for diabetes health practitioners to gain increased knowledge and confidence in using MI, although both knowledge and confidence were still not high post-training. It therefore appears that post-training supervised practice may be important for increasing MI skills. Following two days training plus supervised post-

training practice, the DNEs were able to practice MET in a manner that was consistent with the general principles of MI and satisfy criteria for at least beginning proficiency in MI. Compared to PE, during MET they were more patient-centred, elicited more self-motivational statements, engaged in more reflective listening, with more complex reflections, and were more empathic. It should be noted, however, that the DNEs self-selected into the research, and therefore were likely to have been highly motivated to learn MI. The generalisability of these results is therefore unclear.

The increase in reflective listening in the present research contrasts with the findings of Miller et al (2004) who found a reduction in MI-inconsistent responses (e.g. confrontation) rather than a substantial increase in reflective listening, and Miller & Mount (2001) who found a modest increase in reflections but no decrease in confrontational MI-inconsistent responses. This may be a function of the different practitioners being studied as well the different settings in which they worked. The practitioners in the present research were health professionals with minimal prior training in counselling and therefore had plenty of room to move in terms of development of reflective listening skills, whereas the practitioners in the other two studies had previous counselling skills and therefore were perhaps already utilising reflective listening. Additionally, in the previous studies the practitioners were working in settings providing assistance for people with substance abuse problems (Miller et al., 2004) or in community probation services (Miller & Mount, 2001) in which a MI-inconsistent confrontational style might be more likely to occur, than perhaps in a health service providing care to persons with diabetes as in the present research.

The present research also provides evidence that the changes in the nurse educators' behaviour may have led to changes in the participants' behaviour during MET sessions consistent with MI theory. For example, participants during MET exhibited less resistance and engaged in more change talk than during PE, and the frequency of client change talk increased during MET sessions but decreased during PE. Furthermore, as recommended by Moyers et al (2005), the present research provides evidence that these in-session interactions were linked to post-intervention outcomes, with the participants who received MET making more changes in their diabetes self-management behaviour, with consequent improvements in diabetes outcome, than the participants who received PE.

Additionally, all but one participant in Studies 1-2 who received MET (n=17) either had an increase in their motivation to change or their motivation, as measured by the SOCRATES, remained unchanged post-intervention. In contrast, more than one third of participants who received PE had a decrease in motivation to change post-intervention. As well as providing further support for MI, this finding is also consistent with previous research which found that advice-giving may lead to increased resistance (Patterson & Forgatch, 1985).

MI theory would predict that advice-giving to individuals, particularly in the pre-contemplation or contemplation stage of change, may negatively impact on motivation (Miller & Rollnick, 1991, 2002). The results from the present research, however, suggest that there was no particular stage of change which was more vulnerable to the deleterious effects of advice-giving on motivation.

Further research is needed on whether stages of change are useful in predicting when advice-giving may have a deleterious effect on motivation, or whether there is a stage of change when advice may be beneficial, as well as the best way of measuring motivation to change. Answering these questions would enable health practitioners to be more targeted as to whom they give advice so that it can be maximally effective, and instead to focus on motivation to change for those individuals who are less likely to benefit from advice.

Additionally, it appears that the process of MI, which included the nurse educators and participants working more collaboratively, led to targets for behaviour change which were more specific, realistic and achievable. This may have resulted from the participants playing a greater role in setting the behaviour change targets and therefore setting targets that they considered achievable, as well as the health practitioners being encouraged to facilitate goals that were concrete, small and achievable. Thus, the successful behaviour change outcomes with MET may have, at least in part, been due to the more realistic goals that were set. It is unlikely, however, that the nature of the targets set was the only factor in the successful outcomes with MET, as MET was also superior to PE when less concrete goals (such as dietary compliance) were set.

The two days of training, plus supervised practice of MET, appears sufficient to have enabled the nurse educators to increase their MI skills to the level of beginning proficiency for the ratio of reflections to questions, and competency for the percent of complex reflections and MI consistent responses. Additionally, these changes in the health practitioners' practice appears sufficient to have led to improved self-

management and in turn improved metabolic control. It is unclear, however, whether further enhancement of their MI skills (e.g., to competency for the ratio of reflections to questions) through further training and/or supervision would lead to even greater improvements in diabetes self-management and diabetes outcome. It is also unclear whether the addition of a booster session for participants, for example, 6-months post-MET when the effects appear to have been waning, would have further enhanced the outcome.

In their meta-analysis Hettema et al (2005) found there was an average training time of 10 hours, similar to the present research, with 29% of studies including post-training supervision. They, however, also found better outcomes for studies that did not include a manual to guide MI (i.e., $d=.65$ for studies with no manual compared to $d=.37$ for studies using a manual). It may then be that the outcomes achieved with MET in the present research could be enhanced if a manual was not used. It may, however, be that the manuals used in the studies reviewed by Hettema et al (2005) were overly prescriptive and therefore did not encourage individualised treatment. A standardised manual-based approach to MI, if overly prescriptive, runs the risk of not adhering to the spirit of MI through losing sight of the individual client's readiness to change which may fluctuate within session.

The manual used in the present research was not prescriptive, but rather provided a summary of key MI skills and techniques, and strategies as a base from which the health professionals could add or remove elements dependent on the participants' readiness to change and individual characteristics. As well as this flexibility being important for good MI practice, Doherty et al's research on change counselling in

diabetes “highlighted individual differences and the importance of tailoring any intervention to a person’s specific needs” (p. 266).

A similar debate exists regarding standardised manual-based or individualised CBT (Kendall, Holmbeck & Verduom, 2004). Some studies suggest the superiority of individualised interventions to standardised manual-based interventions (e.g., Ghaderi, 2006; Jacobson, Schmaling, Holtzworth-Munroe, Wood & Follette, 1989), but other studies suggest the superiority of manual-based interventions (e.g., Schulte, Kunzel, Pepping & Schulte-Bahrenberg, 1992; Emmelkamp, Bouman & Blaauw, 1994). Further research into the role, nature, and effect on outcome of manual-guided MI is recommended.

Weaknesses of the present research

The results of the present research should be treated with caution, however, as only a small number of participants were involved in the research. This meant that the statistical analyses were limited by a lack of power. Additionally, the high variability in the goals for change selected by the participants limited the number of replications. The conclusions that can be drawn from the present research, especially regarding the generalisability of the results, should therefore be treated with caution.

There was also a lack of random assignment to condition, although the condition was not selected by the researcher, instead it was based on consecutive referrals. Additionally, for clinical reasons, it was not possible to wait for stable baselines, and lack of control regarding stage change criteria. Furthermore, some of

the self-management data were highly variable, all of which limit the strength of the conclusions which can be drawn. This variability, however, is presumably representative of the variability seen in real clinical experience. This has implications for how research in diabetes self-management is developed and interpreted (i.e., care needs to be taken that observed change is not attributed to an intervention effect, when it may only be a function of the high variability in the data). The present research used coefficients of variation as part of the statistical tests for the metabolic data (HbA1c and lipids), thereby accounting for biological variation (Fraser, 2001).

A further weakness of the present research was the reliance on visual analysis as the sole means of interpreting the diabetes self-management data. While it has been suggested that visual analysis of single-case data is generally reliable and conservative (Baer, 1977; Micheal, 1984; Parsonson & Baer, 1978; 1986), results of empirical studies (Franklin, Gorman, Beasley & Alison, 1996) suggest that this may not always be true. The results of the current study should therefore be treated with caution.

There was also a heavy reliance for the diabetes self-management behaviour on data gathered from self-monitoring. There were few other sources of data available for some of the target behaviours, such as diet and exercise. This, however, was not the case for all of the data. In particular, the use of a blood glucose meter with a built-in memory provided an independent and reliable source of data on both the frequency of SMOBG and blood glucose level.

Additionally, a relatively crude measure of dietary compliance was used. This comprised rating the participants' food records as to whether they were consistent with general recommendations for a diabetic diet, which is a diet that is low in sugar and fat, but high in fibre. A full nutritional analysis of participants' food records would have provided a more thorough measure of dietary compliance. A nutritional analysis, however, would have increased the demands on the participants' self-monitoring, requiring them to be more detailed as to the ingredients and quantity of food consumed. Such demands may then have reduced the frequency and reliability of self-monitoring.

A possible confounding factor in the present research is that the interventions were not similar in terms of intensity, with MET tending to comprise more appointments, and appointments which were of longer duration than PE. It could therefore be argued that the superior outcome for MET was simply due to the duration of intervention, rather than the specific nature of the intervention itself. Treatment duration, however, is unlikely to be the sole factor leading to improved diabetes management, especially given the differential effect MET appeared to have on client change talk and resistance.

Another confounding factor is that the participants in Study 1 were dissimilar at baseline, with MET participants tending to have a longer duration of diagnosis of diabetes, higher average blood glucose, and more diabetes complications. Thus, the results for MET participants may have been overly inflated when compared to PE, with MET participants having more room for improvement than the PE participants.

It can also be argued, however, that the poor status of the MET participants' diabetes compared with the PE participants is evidence of their poor compliance. That the MET participants were able to make changes in their diabetes self-management, with consequent improved metabolic control, after a relatively brief intervention, could be seen as evidence as to the power of MET. Additionally, the participants in Study 2 were more alike at baseline, yet similar results were obtained in Study 2 as in Study 1, with results suggesting the superiority of MET over PE both in terms of improved diabetes self-management and improved metabolic control.

Strengths of the present research

While the numbers are small in the present research, evidence of the replicability (Part B, Study 1) and generality (Study 2) of the findings is provided. MET was found to improve diabetes outcome and enhance diabetes self-management and for patients aged 21-69 years of age with Type 1 and Type 2 diabetes who received MET from either a DNE (Study 1) or dietitian (Study 2), and for whom improvement in a range of diabetes self-management behaviours (e.g., SMOBG, dietary compliance) was a goal.

In the context of working in a routine clinical service, and given the evidence of high variability in some of the dependent measures (especially data from SMOBG), the use of single-case research design also enabled the complexity of, and individual variability in, diabetes treatment to be accommodated, further strengthening the applicability of the findings to real-life clinical situations. The use of single-case design enabled participants' individualised targets for change to be included as

outcome measures, and allowed the consideration of other variables, such as medication changes, which may have influenced outcome.

Additionally, the present research is consistent with the call for more practice based evidence in health care (Glasgow et al., 2006, Glasgow, Davidson, Dobkin, Ockene & Spring, 2006, Green & Glasgow, 2006, Tunis et al., 2003), and follows the recommendations for Practice-based Clinical Trials (PCTs) and Practice-based Behavioural Trials (PBTs) as suggested by Tunis et al (2003) and Glasgow et al (2006), respectively. This meant that two clinically meaningful alternative interventions (i.e., PE and MET) provided by representative clinical staff were compared, with a heterogeneous sample. Additionally multiple outcomes were assessed, including measures of behaviour change at the patient and clinician level; a variety of psychosocial measures; the degree of implementation of the intervention by clinical staff; generalisation across participants, intervention staff and outcomes; as well as cost (i.e., resource utilisation) and patient preferences.

In order to do so a number of barriers for PCTs and PBTs as outlined by Glasgow et al (2006) had to be overcome. In order to maximise generalisability, in-house clinic staff provided the interventions. This meant that the intervention and data collection needed to be planned to fit in with usual clinic practice. The inclusion of clinical staff from the beginning of conceptualisation of the research using principles of PAR facilitated this. As Glasgow et al (2006) point out, “the inclusion of clinical colleagues in target settings is critical....., not only because they can sabotage it (the research) if they are against it but also because they know their clientele and the logistics of working in their setting” (p.10).

Thus, the action research nature of the studies strengthened the applicability of the present research to the real life clinical situation. It enabled the identification of the potential application of MI to diabetes self-management and made use of the interest the diabetes health practitioners had in learning MI skills. A number of important questions were also identified with the diabetes practitioners, including the applicability of MI to their busy clinical situation, training and supervisory needs, the acceptability of MI to patients, and its effectiveness when applied to diabetes. The research was then designed to explore these questions. Additionally, when other opportunities arose to further explore these questions (e.g., the opportunity to run additional training with a larger number of health practitioners), these were built into the research.

Another strength in the present research was that treatment integrity was evaluated, with results suggesting that PE and MET were distinct interventions, and that MET was practiced in a manner consistent with MI. Very few studies examining the application of behaviour change interventions to diabetes self-management provide evidence that the health practitioners engaged in the research were employing the intervention in a consistent fashion (Doherty et al., 2000). Additionally, Hettema et al (2005) in a meta-analysis of 72 MI treatment trials found only 36% of these studies included treatment fidelity checks.

Additional recommendations for future research

The practice-based evidence for the effectiveness of MET and the use of PAR principles in the present research, contributed to the buy-in of clinical staff and management. Thus, in the true nature of PAR (i.e., an ongoing cyclical process of reflection, planning, action, and evaluation) there have been discussions with the author regarding how the MET can be sustained and become part of routine clinical practice, which have raised more questions for future research. These questions include whether the way MI was provided (i.e. in the MET format, with a limited number of sessions over a relatively short time period) is important for positive outcome, and how can greater numbers of health practitioners receive MI training plus the supervised practice which appears important for skills development and transfer into clinical practice (Miller et al., 2004).

Future research also needs to explore whether the results obtained in the present research can be generalised to adolescents with diabetes or ethnic groups with a high incidence of diabetes, such as Maori and Pacific Island People in New Zealand. Although the inclusion age for the present research extended down to 16 years of age, the youngest participants were 21 years of age. There were also no Pacific Island participants in the present research. Additionally, while there were three Maori participants in Study 1, (one of whom was also a participant in Study 2 having received PE in Study 1), the results were mixed for these individuals.

There is reason to believe that MI may be a useful intervention with Maori and Pacific Island People with diabetes. For example, Hettema et al's (2005) meta-

analysis found greater ES for ethnic minority samples ($d=.79$) compared to Caucasian samples ($d=.39$). This is also consistent with Longshore et al's (1999) conclusion that MI was a "culturally congruent" (p.1223) intervention for African Americans because of its emphasis on personal choice, and avoidance of advice-giving and confrontation.

Additionally, research with Pacific Island People with diabetes in New Zealand found that 22% felt uninvolved in their diabetes care (Paddison, Vae'au, Flett & Stephens, 2004) and that the 'doctor-patient' relationship was an important determinant of self-care and health outcomes (Paddison, Faimalie, Flett, Alpass & Stephens, 2004). Given that diabetes is three times more common in Maori and Pacific Island People and their mortality rate in the 40-65 year age range is nearly ten times higher than for other New Zealanders (Ministry of Health, 2000), further research into MI applied to diabetes self-management with Maori and Pacific Island Peoples is recommended.

Adolescence poses a particular challenge for diabetes management. The failure of medication regimens to significantly improve metabolic control during adolescence has led to a focus on educational and psychosocial interventions to optimise treatment for adolescents with diabetes (Viner et al., 2003). Hampson et al (2001), in a systematic review of educational and psychosocial interventions with adolescents with diabetes, however, found very small effect sizes, suggesting that existing treatments are not very effective for this group.

As mentioned in the introduction, MI may be particularly suited to adolescents because of its emphasis on personal responsibility and avoidance of an authoritarian

stance. MI has been used successfully with adolescents with substance abuse problems (Colby et al., 1998; Lawendowski, 1998), and Berg-Smith et al (1999) report positive results with brief MI focused on dietary adherence with adolescents. Additionally, Viner et al (2003) in a pilot non-randomised controlled trial report significant improvements in HbA1c 4-6 months post-intervention compared to no change in controls for adolescents with Type 1 diabetes who attended a group intervention which comprised MET plus solution-focused therapy. It would therefore be useful to evaluate the efficacy of MET applied to diabetes self-management for adolescents with diabetes.

Lastly, MET appears to have been a more expensive intervention (i.e., MET comprised more sessions and sessions of longer duration than PE), as well as the additional costs of training and supervision. Doherty et al (2000) suggest that the extra costs associated with training and extra time with patients associated with behaviour change counselling in diabetes is not unreasonable if it can be justified with evidence, as in the present research, that change counselling leads to actual behaviour change, and subsequent clinically significant improvements in HbA1c, as well as improvements to quality of life.

Working on the premise that most complications of diabetes can be delayed, it has been argued that the increased cost of interventions which delay the onset of diabetes itself or improve diabetes self-management can be expected to save more than they cost (Tuomilehto, Lindstrom, Eriksson, Valle, Hamalainen et al., 2001). Price Waterhouse-Coopers, in a report commissioned by Diabetes New Zealand (an independent association of individuals diagnosed with diabetes, and diabetes health

professionals), estimated that diabetes services in New Zealand cost \$247 million a year (Breakthrough, 2001). This figure does not include the costs of diminished productivity and quality of life. Furthermore, Price Waterhouse-Coopers' projections indicate that the total cost of diabetes can be reduced over 20 years if existing services are increased (Breakthrough, 2001). Under their enhanced services model, if funding was increased and provided for specific and targeted services (MET being a possible example), the predicted outcome over 20 years would be an improvement in the health of those diagnosed with diabetes, with a reduction in diabetes-related complications. Thus, the savings from fewer severe complications in later years would offset the additional spending in earlier years (Breakthrough, 2001).

“We, people with diabetes, are a group of individuals who are unique one from the other. The only thing we have in common is our diabetes and even that might be a different type or might behave differently...; but all of us want to live a good quality life. It is not for you, health professionals, to provide this quality of life. You cannot do this for us. We have to do it for ourselves. You can counsel us with information and advise but it is for us to act and achieve...We need for all health providers to know that the world is changing and the way medicine is provided is changing as well. Chronic disorders like diabetes require the active participation of the affected individual to achieve good results. Many people with diabetes are beginning to awaken. We no longer want to sit on the other side of the desk, quietly nodding our heads. From patients we have become actors. We have become more demanding and understand that our health is in our hands...We have to awaken health professionals who stubbornly insist to act like judges and dictators to become counselors and partners.” (De Alva, M., 2000).

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Appendix 1: Description of Study 1 participants

Reason for referral

PE and MET participants had similar reasons for referral to the DNE (Table 38), with assistance with diabetes management being the main reason for referral. Compliance was specifically mentioned as a problem for one PE and two MET participants, and problems with blood glucose control was mentioned for three PE and two MET participants. GPs were the most frequent referral source (Table 38), although more MET participants were referral from a Diabetes Physician.

Table 38. Summary of referral information

	PE	MET
Reason		
Assistance with diabetes management	5	5
Compliance problem	1	2
High blood glucose control	3	2
Source		
GP	6	5
Diabetes physician	2	4
Other physician	1	0

Diabetes Complications

MET participants experienced more diabetes complications than the PE participants (Table 39). This suggests that their blood glucose is likely to have been higher than the PE participants, but may also reflect the longer duration since diagnosis of diabetes for the MET participants.

Table 39. Diabetes complications experienced by participants

Complications	PE	MET
Retinopathy	4	2
Peripheral neuropathy	0	3
Peripheral vascular disease	0	3
Nepticopathy	0	1
Infections	1	0
Nil	4	4

Other health problems

PE and MET participants, however, were fairly similar in the other health problems they experienced (Table 40), with heart disease and asthma the most frequent health problem experienced by participants in addition to diabetes. While MET participants were experiencing more diabetes-related complications, more PE participants tended to experience multiple health problems (i.e. had more than one health problem in addition to diabetes).

Table 40. Other health problems experienced by participants

Health problem	PE	MET
Heart disease	2	3
Chronic pain	2	0
Psychiatric disorder	0	0
Epilepsy	1	0
Asthma	3	2
Sleep apnoea	1	0
Nil	3	4

Medications

The majority (n=7) of PE participants were prescribed oral medication for their diabetes (Table 41), with only two PE participants prescribed insulin (one in combination with oral diabetes medication) for their diabetes, which is consistent with most PE participants' diagnosis of Type 2 diabetes. Six MET participants, however, were prescribed insulin for their diabetes (Table 41). This in part is due to more (i.e. n=4) MET participants being diagnosed with Type 1 diabetes, but also suggests the worsening status of some of the MET participants' Type 2 diabetes. A small number (i.e., PE n=3, MET n=2) of participants were prescribed lipid-lowering medication (Table 41). No participants were prescribed no medication at all, with a number of participants also prescribed a number (i.e., PE n=6, MET n=4) of other medications (Table 41).

Table 41. Summary of participants' medications

Medication	PE	MET
Oral diabetes	7	3
Insulin	1	6
Combined insulin and oral diabetes	1	0
Lipid lowering	3	2
Antihypertensive	1	1
Other	6	4
Nil	0	0

Employment

PE and MET participants were similar in their employment status (Table 42), with only one PE and MET participant in receipt of welfare assistance due to illness. Participants were engaged in a range of work, with manual work the most common (i.e. PE n=3, MET n=4).

Table 42. Employment status of participants

Employment	PE	MET
Manual	3	4
Retail	1	1
Business	0	1
Unpaid work	2	0
Tertiary student	0	1
Retired	2	1
Sickness beneficiary	1	1

Case Descriptions

Case 1. A 40 year old Caucasian female with Type 2 diabetes diagnosed at 35 years of age. She had a history of recurrent vaginal thrush which was attributed to her diabetes, but no other known diabetes-related complications. Her diabetes was managed through diet and oral medication (Glipizide and Metformin). She was also prescribed Bezafibrate for dyslipidaemia. Her diabetes medication remained unchanged through the study. She was seen for ongoing support by the DNE three times during the 3-month follow-up period.

Case 2. A 59 year old Caucasian female, with Type 2 diabetes diagnosed at 55 years of age. She had no known diabetes-related complications. Her diabetes was managed by diet and oral medication (Metformin and Glibenclamide). She was also prescribed Bezafibrate for dyslipidaemia, the dose of which had been increased at 12-month follow-up. She was commenced on Metformin by her GP during the 3-month follow-up period. Also, she was referred by the DNE to a dietitian who saw her on one occasion only.

Case 3. A 41 year old Caucasian male with Type 2 diabetes diagnosed at 37 years of age. He had no known diabetes-related complications. His diabetes was managed by diet, oral medication (Metformin), and insulin injections (Penmix). He was referred by the DNE to a dietitian whom he saw on only one occasion during the 3-month follow-up period. At 12-month follow-up he was no longer taking oral medication for his diabetes.

Case 4. A 54 year old Caucasian female with Type 2 diabetes diagnosed at 33 years of age. She had diabetic retinopathy. Her diabetes was managed by diet and oral medication (Metformin and Glipizide). Her diabetes medication remained unchanged throughout the study.

Case 5. A 31 year old Caucasian female with Type 1 diabetes diagnosed at 13 years of age. She had progressive diabetic retinopathy. Her diabetes was managed by diet and insulin injections (Humalog and Humulin N), which remained unchanged throughout the study. She was referred by the DNE to a clinical psychologist and was seen for assessment of psychological factors affecting diabetes management on two

occasions during the 2-week follow-up period and for three treatment sessions during the 3-month follow-up. She was also seen by a dietitian on two occasions during the 3-month follow-up period. Unfortunately, 12-month follow-up questionnaire data are not available.

Case 6. A 50 year old Caucasian female with Type 2 diabetes diagnosed at 45 years of age. She had no known diabetes-related complications. Her diabetes was managed by diet and oral medication (Glipizide and Metformin). Her diabetes medication remained unchanged throughout the study.

Case 7. A 45 year old Maori male with type 2 diabetes diagnosed at 44 years of age. There were no diabetes-related complications noted in his file, although he reported erectile dysfunction which can be a diabetes-related complication. His diabetes was managed by diet and oral medication (Metformin). His diabetes medication remained unchanged throughout the study. He was referred by the DNE to a dietitian and seen on two occasions, once in the 2-week follow-up and once during the 3-month follow-up period.

Case 8. A 64 year old Caucasian male with Type 2 diabetes diagnosed at 61 years of age. He had diabetic retinopathy. His diabetes was managed by diet and oral medication (Glipizide and Metformin). His diabetes medication remained unchanged throughout the study. He was seen by the DNE for support on one occasion during the 3-month follow-up period.

Case 9. A 56 year old Caucasian female with Type 2 diabetes diagnosed at 52 years of age. She had no known diabetes related complications. Her diabetes was managed by diet alone. She was, however, prescribed Simvastatin for dyslipidaemia, which had been stopped at 12-month follow-up. She was referred by the DNE to a dietitian and was seen three times during follow-up. In the intervening period between the end of PE and being contacted about participation in Part B (MET) of the study she had been diagnosed with, and received treatment for, mental health problems of anxiety and depression.

Case 10. A 30 year old Caucasian male with Type 1 diabetes diagnosed at 13 years of age. He had retinopathy, nephropathy, and sensory peripheral neuropathy, all attributed to his diabetes. His diabetes was managed by diet and insulin injection (Actrapid and Monotard), which was changed to Humalog and Humlin as a result of discussions with the DNE during MET. He was referred by the DNE to a dietitian with whom he had one appointment in the fourth week of treatment.

Case 11. A 68 year old Caucasian male with Type 2 diabetes diagnosed at 53 years of age. He had peripheral vascular disease and peripheral neuropathy, which were attributed to his diabetes. His diabetes was managed by diet and insulin injections (Protaphane and Penmix). At 12-month follow-up he was also prescribed Benzafibrate for dyslipidaemia.

Case 12. A 60 year old Caucasian male with Type 2 diabetes diagnosed at 41 years of age. He had diabetic retinopathy and peripheral vascular disease attributed to

his diabetes. His diabetes was managed by diet and insulin (Humulin and Humulog). His diabetes medication remained unchanged throughout the study.

Case 13. A 21 year old Caucasian female with Type 1 diabetes diagnosed at 14 years of age. She had no known diabetes-related complications. Her diabetes was managed by diet and insulin injections (Humulin and Humulog). Her diabetes medication remained unchanged throughout the study.

Case 14. A 54 year old Caucasian female with Type 2 diabetes diagnosed at 41 years of age. She had retinopathy, with threatened maculopathy, which were attributed to her diabetes. Her diabetes was treated by diet and oral medication (Metformin and Glipizide). She was also prescribed Simvastatin for dyslipaemia. Her medication, however, was altered for the last 6-months of follow-up, with the addition of insulin injections (Penmix) and Glipizide was stopped.

Case 15. A 21 year old Caucasian female with Type 1 diabetes diagnosed at 14 years of age. She had no known diabetes-related complications. Her diabetes was managed with diet and insulin injections (Humulog and Humulin). Her diabetes medication remained unchanged throughout the study.

Case 16. A 36 year old Maori male with Type 2 diabetes diagnosed at 25 years of age. He had peripheral neuropathy and vascular disease, attributed to his diabetes. His diabetes was managed with diet and oral medication (Metformin and Glipizide). His diabetes medication remained unchanged throughout the study.

Case 17. A 59 year old Maori woman with Type 2 diabetes diagnosed at 48 years of age. She had no known diabetes-related complications. Her diabetes was managed by diet and oral medication (Metformin and Glicazide). At 3-month follow-up, however, her diabetes medication was changed with the addition of insulin injections (Penmix), and Glicazide was stopped. Bezafibrate for dyslipaemia was also added at this time.

Case 18. A 47 year old Caucasian male with Type 1 diabetes diagnosed at 32 years of age. He had no known diabetes-related complications. His diabetes was managed by diet and insulin injections (Humalog and Humulin). At 12-month follow-up he was also being prescribed Atorvasatin for dyslipidaemia.

MOTIVATIONAL ENHANCEMENT THERAPY

THERAPIST MANUAL

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1 INTRODUCTION TO MOTIVATIONAL ENHANCEMENT THERAPY (MET)

MET is a brief, systematic psychotherapeutic intervention based on the principles of motivational interviewing. It is a treatment approach which aims to motivate patients to make changes rather than provide a detailed step-by-step guide to behaviour change. MET was developed for the purposes of Project MATCH, a large US multisite, study of three outpatient treatments for alcohol dependence, including motivational enhancement therapy.

1.1 Nonspecific factors of MET

Six general therapeutic factors hypothesized to be active ingredients of effective brief therapies are summarized by the acronym FRAMES as outlined below. These factors guide the MET therapist in their general stance and therapeutic interaction in therapy.

- FEEDBACK of personal impairment and risk
 - emphasis on personal RESPONSIBILITY for change
 - clear ADVICE to change
 - a MENU of alternative change options
 - therapist EMPATHY
 - facilitation of patient SELF-EFFICACY or optimism

1.2 Specific principles of MET

The MET approach begins with the assumption that the responsibility and capability for change lie within the patient. The therapist's task is to create a set of conditions that will enhance the patient's own motivation for and commitment to change. Rather than relying on therapy sessions as the primary locus of change, the therapist seeks to mobilize the patient's inner resources as well as those inherent in the patient's natural helping relationships.

In motivational interviewing, the therapist does not confront the patient who denies that their behaviour (e.g. inadequate diabetes self-care) is a problem. Instead, the therapist uses techniques designed to increase the patient's own level of self-confrontation and reappraisal about their behaviour. The therapist avoids taking an authoritarian, paternalistic role and reinforces the principle that responsibility for change lies with the individual. Although motivational interviewing is not coercive or confrontational, it involves clear strategies and skills aimed at increasing patients' motivation for change.

Five key clinical principles guide the conduct of MET from a technical point of view.

- *Express Empathy
- *Develop Discrepancy
- *Avoid Argumentation
- *Roll with Resistance
- *Support Self-efficacy

**Express Empathy*

The MET therapist seeks to communicate respect for the patient. Communications that imply a superior/inferior relationship between therapist and patient are avoided. The patient's freedom of choice and self-direction are respected and promoted so that the message given is that only they can decide to make a change in their behaviour and carry out that choice. Much of MET is listening rather than telling. Persuasion is gentle, subtle, always with the assumption that change is up to the patient. Reflective listening (accurate empathy) is a key skill in motivational interviewing. It communicates an acceptance of patients as they are, while also supporting them in the process of change.

****Develop Discrepancy***

Motivation for change occurs when people perceive a discrepancy between where they are and where they want to be. The MET approach specifically seeks to enhance and focus the patient's attention on such discrepancies. In certain cases (e.g. precontemplative patients) it may be necessary first to develop such discrepancy by raising patients' awareness of the personal consequences of their behaviour. When patients enter treatment in the later contemplative stage, it takes less time and effort to move them along to the point of determination for change.

**** Avoid Argumentation***

If handled poorly, ambivalence and discrepancy can resolve into defensive coping strategies that reduce the patient's discomfort but do not alter their behaviour (e.g. diabetes self-care and related risks). The MET style explicitly avoids direct argumentation which tends to evoke resistance. The therapist does not seek to prove or convince by force of argument. When MET is conducted properly, the patient and not the therapist voices the arguments for change.

**** Roll with Resistance***

How the therapist handles patient "resistance" is a crucial and defining characteristic of the MET approach. MET strategies do not meet resistance head on, but rather "roll with" the momentum, with a goal of shifting patient perceptions in the process. New ways of thinking about problems are invited, but not imposed. Ambivalence is viewed as normal, not pathological, and is explored openly. Solutions are usually evoked from the client rather than provided by the therapist.

**** Support Self-efficacy***

People who are persuaded that they have a serious problem will still not move toward change unless there is hope for success. "Self-efficacy" is a critical determinant of behaviour change. Self-efficacy is the belief that one can perform a particular behaviour or accomplish a particular task as opposed to whether or not they see the goal or outcome as desirable. In this case, patients must be persuaded that it is possible to change their own behaviour and thereby reduce diabetes related problems. In other words, the patient's perception of helplessness, even in the face of acceptance that they need to improve their management of their diabetes, is the focus.

1.3 Measurement of motivation

Motivational interviewing has been linked with the stages-of-change model [Prochaska & DiClemente 1982] where motivation is viewed as a person's current "readiness for change". Six separate stages of change have been described as precontemplation, contemplation, determination, action, maintenance and relapse [Prochaska & DiClemente 1986]. Latterly, "determination" has been replaced by "preparation" to emphasize the cognitive adjustments patients make prior to action phase [Prochaska et al. 1994]. The determination stage will be referred to as preparation in this manual. People who are not considering change in their behaviour (e.g. diabetes self-care) are described as Precontemplators. The Contemplation stage entails individuals' beginning to consider both that they have a problem and the feasibility and costs of changing that behaviour. As individuals progress, they move on to the Preparation stage, where the decision is made to take action and change. Once individuals begin to modify the problem behaviour, they enter the Action stage before moving to a Maintenance stage where change is sustained. If these efforts fail, a Relapse occurs and the individual begins another cycle. Most people who relapse go through the cycle again and it is observed that several revolutions through this cycle are often needed to learn how to maintain change successfully.

For the MET therapist the Contemplation and Preparation stages are most critical. The objective is to help patients seriously consider two basic issues. The first is how much of a problem their behaviour (inadequate diabetes self-care) is, and how it is affecting them (both positively and negatively). Tipping the balance of these pros and cons of diabetes self-care toward change is essential for movement from contemplation to preparation. Second, the patient in contemplation assesses the possibility and the costs/benefits of changing the problem behaviour. Patients consider whether they will be able to make a change and how that change will affect their lives. In the Preparation stage, patients develop a firm resolve to take action. That resolve is influenced by past experiences with change attempts. Individuals who have made unsuccessful attempts to change their diabetes self-care in the past need encouragement to decide to go through the cycle again.

1.4 Differences between MET and Patient Centred Therapy (PCT)

In PCT the therapist does not direct treatment but follows the patient's direction wherever it may lead, using the specific principles of PCT. In contrast, MET employs systematic strategies toward specific goals. In MET the therapist actively works to create discrepancy and to channel it toward behaviour change. MET is a directive and gently persuasive approach focused on the patient's problematic behaviour (diabetes self-management), in contrast to PCT, which is essentially nondirective, more passive and not necessarily focused on problem behaviour). The following are key differences between the two therapies in tabular form [adapted from Miller and Rollnick 1991].

PATIENT-CENTRED	MOTIVATION ENHANCEMENT
Allows the patient to determine the content and direction of sessions, which may not be focused on diabetes at all.	Systematically directs the patient toward motivation for change with a focus on diabetes self-care.
Avoids injecting any advice or feedback from the therapist.	Offers the therapist's own advice and feedback where it is likely to facilitate or consolidate change.
Empathic reflection is used noncontingently and thus not used to specifically focus on changing diabetes self-care behaviour.	Empathic reflection is used selectively to elicit self-motivational statements and reinforce change intentions.
Explores the patient's conflicts and feelings in the present.	Seeks to create and amplify the patient's discrepancy in order to enhance motivation for change.

2. THE PRACTICE OF MOTIVATIONAL ENHANCEMENT THERAPY

Motivational counselling can be divided into two major phases: building motivation for change and strengthening commitment to change.

2.1 Phase 1: Building Motivation for Change

Although patients will vary widely in their readiness to change, most are likely to enter the treatment process somewhere in the contemplation stage. They may be dabbling with taking action but still need consolidation of motivation for change. Phase 1 may be thought of as tipping the motivational balance. One side favours the status quo (e.g. maintaining previous unhealthy diet), whereas the other favours change. The former side is weighed down by perceived positive benefits from not changing and feared consequences of change. Weights on the other side consist of perceived benefits of changing diabetes self-care behaviour and feared consequences of continuing unchanged. The therapist's task is to shift the balance in favour of change. Eight techniques to achieve this are now described.

2.1.1 Eliciting Self-Motivational Statements

When people speak in a new way, their beliefs and values tend to shift in that direction. The worst persuasion strategy is one that evokes defensive argumentation from the person. The MET therapist seeks to elicit from the patient certain kinds of statements that are self-motivating, such as, being open to input about diabetes self-care, acknowledging real or potential problems related to not changing, expressing a need, desire or willingness to change.

There are several ways to elicit such statements from patients. One is to ask for them directly, via open-ended questions for example *“what makes you think you need to make a change to your diabetes management”*. Once this process is rolling, simply keep it going by using reflective listening (see below). If things slow down then invite comment about general areas such as health problems, relationship difficulties, work difficulties, financial issues etc.

If you encounter difficulties in eliciting patient concerns, another strategy is to employ gentle paradox to evoke self-motivational statements. In this table-turning approach, you subtly take on the voice of the patient’s resistance and thereby evoking from the patient the opposite side. For example, *“I’m not sure how much you are interested in changing, or even in taking a careful look at your diabetes. It sounds like you might be happier just going on as before”*.

In general, however, the best opening strategy for eliciting self-motivational statements is to ask for them; for example, *“Tell me what concerns you about your diabetes”*.

2.1.2 *Listening with Empathy*

Eliciting self-motivational statements is one thing to begin with, but it is crucial how you respond to what patients initially say. The therapeutic skill of accurate empathy or reflective listening is an optimal response within MET. The therapist listens carefully to what the patient says then reflects it back, often in a slightly modified form. Acknowledgement of the patient’s feeling state may also be included. The advantages of this strategy include:

- it is unlikely to evoke resistance
- it encourages the patient to keep talking
- it communicates respect and caring and builds a working therapeutic alliance
- it clarifies for the therapist exactly what the patient means, and
- it can be used to reinforce ideas expressed by the patient.

This last characteristic is particularly important because you can reflect quite selectively self-motivational statements related to changing behaviour.

2.1.3 *Questioning*

Questioning is an important therapist response in MET. Rather than telling patients how they should feel or what to do, the therapist asks patients about their own feelings, ideas, concerns and plans. Elicited information is then responded to with empathic reflection, affirmation or reframing (see below).

2.1.4 *Presenting Personal Feedback*

In the first session of MET, key feedback is given, with opportunity made for discussion. Information should be provided in a neutral and non-personal way, with consideration of the patient’s readiness to receive information. This should be preceded with a question such as: *“I wonder, would you be interested in knowing more about ...?”*

An important part of this process is monitoring and responding to the patient during the feedback. Allow time for the patient to respond verbally. Use reflective listening to reinforce self-motivating statements that emerge during this time. Also respond reflectively to resistance statements, perhaps reframing them or embedding them in a double-sided reflection.

Often a patient will respond nonverbally, and it is possible also to reflect these reactions. A sigh, a frown, a slow sad shaking of the head, a snort or tears can communicate a reaction to the feedback. The therapist can respond to these with a reflection of the apparent feeling.

If the patient is not volunteering reactions, either verbally or non-verbally, it is wise to pause periodically during the feedback process and ask a question such as *“What do you make of this?”* or *“Does this make sense to you?”*.

See Appendix 2 for outline of technique.

2.1.5 *Affirming the Patient*

You should seek opportunities to affirm and compliment the patient sincerely. Such affirmations can be beneficial in a number of ways, including:

- strengthening the working relationship
- enhancing the attitude of self-responsibility and empowerment
- reinforcing effort and self-motivational statements, and
- supporting patient self-esteem.

Some examples are, *“I’m impressed how you’ve hung in there during this feedback which must’ve been pretty rough”* or *“You’ve really had some good ideas for how you might change today”*.

2.1.6 *Handling Resistance*

Patient resistance is a legitimate concern. Failure to comply with a therapist’s instructions and resistance behaviours within treatment sessions (e.g. arguing, interrupting, denying a problem) are responses that predict poor treatment outcome. What too few therapists realize however, is the extent to which such patient resistance is powerfully affected by the therapist’s own style. An important goal in MET is to avoid evoking patient resistance (antimotivational statements) in the first instance. A first rule of thumb is never meet resistance head on. Don’t argue, judge, threaten, attempt to persuade with logic or evidence, interpret, confront or be sarcastic. Even direct questions as to why the patient is “resisting” generally serve to elicit further defense of the antimotivational stance of the patient. If a therapist finds themselves in the position of arguing with the patient, shift strategies, deflect resistance. This can be done in the following five ways.

- simple reflection – simply reflecting what the patient is saying sometimes elicits the opposite
- reflection with amplification – a modification is to reflect but exaggerate or amplify what the patient is saying to the point where the patient is likely to disavow it. Subtlety is required as exaggeration can elicit hostility.
- double-sided reflection – if a patient offers a resistance statement, reflect it back with the other side included (based on previous statements made by the patient in the session if possible).
- shifting focus – another strategy is to defuse resistance by shifting attention away from the problematic issue.
- rolling with resistance – resistance can also be met by rolling with it instead of opposing it. There is a paradoxical aspect to this strategy which often will bring the patient back to a balanced or opposite perspective. This strategy can be particularly useful with patients who present in a highly oppositional manner and seem to reject every idea or suggestion.

2.1.7 *Reframing*

Reframing is a strategy whereby the patient is invited to examine their perceptions in a new light or reorganized form. The general idea in reframing is to place the problem behaviour in a more positive light, which in itself can have a paradoxical effect (prescribing the symptom), but to do so in a way that causes the person to take action to change the problem. Placing problems in a more positive or optimistic frame helps communicate that the problem is solvable and changeable.

2.1.8 *Summarizing*

It is useful to summarize periodically during a session, particularly toward the end of a session. This amounts to a longer, summary reflection of what the patient has said. It is especially useful to repeat and summarize the patient's self-motivational statements. Elements of reluctance or resistance, may be included in the summary, to prevent a negating reaction from the patient.

2.2 **Phase 2: Strengthening Commitment to Change**

2.2.1 *Recognizing Change Readiness*

The eight strategies above are designed to build motivation and to help tip the patient's decisional balance in favour of change. A second major process in MET is to consolidate the patient's commitment to change, once sufficient motivation is present. Timing is a key issue. Within the Prochaska and DiClemente model, this is the Preparation stage, when the balance of contemplation has tipped in favour of change and the patient is ready for action.

There are no universal signs of crossing over into the Preparation stage. Some changes you might observe include, the patient stops resisting and raising objections, the patient asks fewer questions, the patient appears more settled, resolved, unburdened or peaceful, the patient makes self-motivational statements indicating a decision to change, the patient begins imagining life after a change.

Here is a checklist of issues to assist the therapist in determining a patient's readiness to accept, continue in, and comply with a change programme.

- has the patient missed previous appointments or cancelled prior sessions without rescheduling?
- if the patient was coerced in some way into treatment, have they discussed with you their reactions to this involuntariness?
- does the patient show indecision or hesitancy about scheduling future sessions?
- is the treatment being offered quite different from what was expected or what the patient has experienced in the past? If so, have these differences and the patient's reactions been discussed?
- does the patient seem to be very guarded during sessions or otherwise seem to be hesitant or resistant when a suggestion is offered?
- does the patient perceive involvement in treatment to be a degrading experience rather than a "new lease on life"?

If the answers to these questions suggest a lack of readiness for change, it might be valuable to explore further the patient's uncertainties and ambivalence about change. It is also wise to delay any decision-making or attempts to obtain firm commitment to a plan of action. For many patients, there may not be a clear point of decision or determination; the shift from contemplation to action may be a gradual, tentative transition rather than a discrete decision.

It is also important to remember that even when a patient appears to have made a decision and is taking steps to change, ambivalence is still likely to be present. Avoid assuming that once a client has decided to change, Phase 1 strategies are no longer needed. Likewise, you should proceed carefully with patients who make a commitment to change too quickly or too emphatically.

In any event, a point comes when you should move toward strategies designed to consolidate commitment. The following seven strategies are useful once the initial phase has been passed and the patient is moving toward change. The goal in Phase 2 is to elicit from the patient some ideas and ultimately a plan for what to do about their diabetes.

2.2.2 Discussing a Plan

The key shift for the therapist is from focusing on reasons for change (building motivation) to negotiating a plan of change. Patients may initiate this by stating a need or desire to change or by asking what they could do. Alternatively, the therapist may signal this shift (and test the water) by asking a transitional question such as, "Where does this leave you in terms of your diabetes? What have you been thinking of doing?"

It is not your task to prescribe a plan for how the patient should change or to teach specific skills for doing so. The overall message remains "Only you can change your behaviour (diabetes self-care), and it's up to you". Reflecting and summarizing continue to be good therapeutic responses as more self-motivational statements and ideas are generated.

2.2.3 Communicating Free Choice

An important and consistent message throughout MET is the patient's responsibility and freedom of choice. Reminders of this theme should be included during Phase 2. "No one can change your behaviour for you. Only you can do it".

2.2.4 Consequences of Action and Inaction

A useful strategy is to ask the patient to anticipate the result if they continue as before. What would be the likely consequences? It may be useful to make a written list of the possible negative consequences of not changing. Similarly, the anticipated benefits of change can be generated by the patient. A complete picture will be gained by also discussing what the patient fears about changing.

One possibility here is to construct a formal "decisional balance" sheet, by having the patient generate (and write down) the pros and cons of change options. What are the positive and negative aspects of continuing as before? What are the possible benefits and costs of making a change in diabetes management?

2.2.5 Information and Advice

Often patients will ask for key information as important input for their decisional process. The therapist should provide accurate, specific information. It is also helpful afterwards to ask for the patient's response to this information, with an open-ended question such as: "What do you make of this?"

Patients may also ask for advice. "What do you think I should do?" It is quite appropriate to provide your own views in this circumstance, with a few caveats.

It is often helpful to provide qualifiers and permission to disagree. *"I can certainly give you my opinion, but you're the one who has to make up your mind in the end".*

Being just a little resistive in this situation can be useful. *"I guess I'm concerned that if I give you my advice, then it looks like I'm the one deciding instead of you. Are you sure you want my opinion?"* Within this general set, feel free to give the patient your best advice as to what change should be made, specifically with regard to the patient's diabetes management, (e.g. *"I think you need to take your insulin"*); the need for the patient and their "significant other" to work together, general kinds of changes, (e.g. find new ways to spend time that don't involve eating).

The therapist, however, should not prescribe specific strategies or attempt to train specific skills. This challenge is turned back on the patient, *"How do you think you might be able to do that?"*

A patient may ask for information you do not have. Do not feel obliged to know all the answers. It is fine to say that you do not know, but will find out, You can offer to research a question and get back to the patient at the next session or by telephone.

2.2.6 *Dealing with Resistance*

The same principles used for defusing resistance in Phase 1 also apply here. Reluctance and ambivalence are not challenged directly but rather can be met with reflection or reframing. Gentle paradoxical statements may also be useful during the commitment phase of MET. One form of such statements is permission to continue unchanged, *"Maybe you'll decide that it's worth it to you to keep on the way you have been, even though it's costing you"*.

2.2.7 *The Change Plan Worksheet*

The Change Plan Worksheet (CPW) is to be used during Phase 2 to help in specifying the patient's action plan (see Appendix 1). You can use it as a format for taking notes as the patient's plan emerges. Do not start Phase 2 by filling out the CPW. Rather, the information needed for the CPW should emerge through the use of the skills described above. Use the CPW as a guide to ensure that you have covered the following aspects of the patient's plan.

The changes I want to make are...

- In what ways or areas does the patient want to change? Be specific. It is wise to include goals that are positive (wanting to begin, increase, improve, do more of something) and not only goals that could be accomplished through general anaesthesia (to stop, avoid, or decrease behaviours)

The most important reasons why I want to make these changes are...

- What are the likely consequences of action and inaction? Which motivations for change seem most impelling to the patient?

The steps I plan to take in changing are...

- How does the patient plan to achieve the goals? Within the general plan and strategies described, what are some specific, concrete first steps that the patient can take? When, where, and how will these steps be taken?

The ways other people can help me are...

- In what ways could other people help the patient in taking the steps toward change? How will the patient arrange for such support?

I will know that my plan is working if...

- What does the patient hope will happen as a result of this change in plan? What benefits could be expected from this change?

Some things that could interfere with my plan are...

- Help the patient to anticipate situations or changes that could undermine the plan. What could go wrong? How could the patient stick with the plan despite these problems or setbacks?

It is important to make a copy so that the original is given to the patient and a copy retained for the file.

2.2.8 Recapitulation

Toward the end of the commitment process, as you sense that the patient is moving toward a firm decision for change, it is useful to offer a broad summary of what has transpired. This may include a repetition of the reasons for concern uncovered in Phase 1, as well as new information developed during Phase 2. Emphasis should be given to the patient's self-motivational statements, the patient's plans for change and the perceived consequences of changing and not changing. Use your notes on the Change Plan Worksheet as a guide. End with an inquiry whether this is right or not. "*Do I have it right? What have I missed out?*"

If the patient offers additions or changes, reflect these and integrate them into your recapitulation. Also note them on the Change Plan Worksheet.

2.2.9 Asking for Commitment

After you have recapitulated the patient's situation and responded to additional points and concerns raised by the patient, move toward getting a formal commitment to change. In essence, the patient is to commit verbally to take concrete, planned steps to bring about the needed change. The key question (not necessarily in these words) is: "*Are you ready to commit yourself to doing this?*"

As you discuss this commitment, also cover the following points:

Clarify what, exactly, the patient plans to do. Give the patient the completed Change Plan Worksheet and discuss it.

Reinforce what the patient perceives to be likely benefits of making a change, as well as the consequences of inaction.

Ask what concerns, fears, or doubts the patient may have that might interfere with carrying out the plan.

Ask what other obstacles might be encountered that could divert the patient from the plan. Ask the patient to suggest how they could deal with these.

Remind the patient that you will be seeing them for two follow-through sessions (scheduled in two weeks and four weeks time respectively) to see how she/he is doing.

If the patient is willing to make a commitment, ask him/her to sign the Change Plan Worksheet and give them the signed original, retaining a copy for your file.

Some patients are unwilling to commit themselves to a change goal or program. When patients remain ambivalent or hesitant about making a written or verbal commitment to change their behaviour, you may ask them to defer the decision until later. A specific time should be agreed upon to re-evaluate and resolve the decision. Such flexibility provides patients with the

opportunity to explore more fully the potential consequences of change and prepare themselves to deal with the consequences. Patients should not feel coerced into making a commitment before they are ready to take action. If they feel coerced, patients may withdraw prematurely from treatment, rather than “lose face” over the failure to follow through on a commitment. When arranging a deferment, it is helpful to express explicit understanding and acceptance of patients’ ambivalence, as well as confidence in their ability to resolve the dilemma.

2.3 Phase 3: Follow-through Strategies

Once a strong base of motivation for change has been established (Phase 1) and the patient’s commitment to change has been obtained (Phase 2), MET focuses on follow-through. This may occur as early as the second session, depending on the patient’s progress. Three processes are involved in follow-through.

2.3.1 Reviewing Progress

Begin a follow-through session with a review of what has happened since your last session. Discuss with the patient what commitment and plans were made and explore what progress the patient has made toward these. Respond with reflection, questioning, affirmation and reframing as before. Determine the extent to which previously established goals and plans have been implemented.

2.3.2 Renewing Motivation

The Phase 1 processes can be used again to renew motivation for change. The extent of this renewal depends on your judgement of the patient’s current commitment to change. This may be assessed by asking patients what they remember as the most important reasons for changing their diabetes self-care behaviour.

2.3.3 Redoing Commitment

The Phase 2 processes can also be continued during follow-through. This may simply be a reaffirmation of the commitment made earlier. If the patient has encountered significant problems or doubts about the initial plan, however, this is a time for re-evaluation, moving toward a new plan and commitment. Seek to reinforce the patient’s own sense of autonomy and self-efficacy – an ability to carry out self-chosen goals and plans.

3. THE STRUCTURE AND CONDUCT OF MOTIVATIONAL ENHANCEMENT THERAPY SESSIONS

3.1 Introduction

This section of the manual describes how the four sessions of MET are to be conducted over the six weeks treatment period in the Brief Treatment Programme.

Prior to these four sessions, the patient will have been briefed on what MET entails at the time of giving consent to participate in the study. It is important, however, to check that the patient understands the rationale for MET at the outset.

3.2 Aims of the Therapy

The three overall aims of the four sessions of MET are linked with the three phases of therapy as follows:

- Phase 1: building motivation for change
- Phase 2: strengthen commitment to change
- Phase 3: facilitate follow-through of change

3.3 Specific Techniques to be used

The overall aims of MET are to be achieved by utilizing the following specific therapy techniques (outlined in the previous section):

- Phase 1: *Building Motivation for Change***
- Eliciting Self-Motivational Statements
 - Listening with Empathy
 - Questioning
 - Presenting Personal Feedback
 - Affirming the Patient
 - Handling Resistance
 - Reframing
 - Summarizing

In this initial phase the strategies from the Menu of Strategies (Table 1), using the specific techniques above, may be helpful in building motivation for change. They should be used flexibly to fit with each patient's situation and state of change and are ordered according to degree of readiness to change.

Table 1. Motivational interviewing strategies

MENU OF STRATEGIES	
Phase 1	<ol style="list-style-type: none"> 1. Typical day 2. Agenda setting chart 3. Personal dissonance
Phase 2	<ol style="list-style-type: none"> 4. Good things and the less good things 5. Problems and concerns 6. Life satisfaction – the present and the future 7. Costs and benefits 8. Constructing a decision balance 9. Helping with decision-making

Specific Strategies:

(i) TYPICAL DAY

The patient is encouraged to talk about their current behaviour in detail within a non-pathological framework. This can be introduced with the following:

“Can we spend the next 5-10 minutes going through a typical day from beginning to end. (Identify a recent typical day, e.g. yesterday). What happened, how did you feel, and where did your diabetes fit in? Let’s start at the beginning...”

(ii) AGENDA SETTING

The patient is encouraged to make decisions about where to take the consultation by the use of an agenda setting card (Appendix 1), which is used to structure the initial discussion. The card can be introduced as follows:

“These are some of the things which we like to talk with people with diabetes about. What about you today?” Would you like to talk about any of these, or do you have something else (pointing to the blank spaces) you would prefer to talk about?”

Should the patient choose an issue in the blank space, this does not mean that the remainder of the session should be used with this topic. Patients should be encouraged to move onto the topic of diabetes management.

(iii) PERSONAL DISSONANCE

The aim of this strategy is to create dissonance between the patient’s positive image of themselves as a person on the one hand and a negative image of themselves on the other. A suggested line of questioning is as follows:

“Give me some words that describe your positive points as a person.”

“Now give me some words that describe you as you have been with managing your diabetes.”

“How do these two fit together?”

(iv) GOOD THINGS – LESS GOOD THINGS

The patient is invited to firstly outline the positive things about continuing as they are and then conversely the negative things. Some suggested questions are:

“What are the less good things that managing your diabetes does for you.”

“Let’s flip the coin. Tell me about the good things that managing your diabetes does for you.”

See Appendix 2 for outline of strategy.

NB Remember that in practical terms the outcome sought from Phase 1 is that the patient is beginning to get ready to take action.

Phase 2: Strengthening Commitment to Change
 Recognizing Change Readiness
 Discussing a Plan
 Communicating Free Choice
 Consequences of Action and Inaction
 Information and Advice
 Dealing with Resistance
 The Change Plan Worksheet
 Recapitulation
 Asking for Commitment

In this phase the Phase 2 strategies from the Menu of Strategies (Table 1) can be used. They are essentially aspects of the techniques “Consequences of Action and Inaction”.

(v) PROBLEMS AND CONCERNS

The patient is encouraged to talk about specific individualized problems and concerns they have about their diabetes. A suggested line of questioning is as follows:

“What problems are you experiencing from your diabetes?”

“What concerns do you have about your diabetes?”

“What else, what other concerns, do you have?”

This strategy ends with a summary which highlights not only these problems and concerns, but also the positive benefits of continuing as they are currently (not changing diabetes self-care).

See Appendix 2 for strategy outline.

(vi) LIFE SATISFACTION

In this strategy, the patient is encouraged to think about their current satisfaction with life and what the future looks like both if they continue as they are and if they improve their management of their diabetes.

Suggested questions are:

“How have things changed for you because of your diabetes?”

“What will happen if you continue as you are now?”

“If things are to improve, what needs to be different?”

(vii) COSTS AND BENEFITS

For this, the patient is invited to weigh up the pros and cons of changing their behaviour (diabetes self-care).

Suggested questions are:

“What would be some of the costs of changing?”

“What would be the benefits of changing?”

(viii) CONSTRUCTION OF DECISION BALANCES

These involve generating the pros and cons of change options which may be the outcome of the two strategies above “Life Satisfaction” and “Costs and Benefits”. It is often good to write these down in the form of balance sheets and given to the patient. They may include:

- (a) reasons to continue as before and reasons to change;
- (b) short term and long term +ve and –ve consequences of changing or staying the same;
- (c) +ve and –ve consequences for self and for others, and self-approval rating for self and from others.

In each of these balances the factors which support change are to be emphasized over those that may maintain the status quo.

The patient should be given a copy of the balance sheet (Appendix 1) at the end of the session.

NB Remember that in practical terms the outcome sought from Phase 2 is that a plan of action has been developed.

(ix) HELPING WITH DECISION MAKING

This should only be used with patients who indicate some desire to make a decision to change. The interviewer needs to be careful not to push too far and produce a retreat from the patient. Therefore the following opening question is recommended:

“Where does that leave you now?”

This can then be followed up by questions which elicit, rather than impose, possible solutions/targets for behaviour change, such as:

“There is no one solution to this problem, but many. I can tell you about what has worked for others, but in the end, you will be the best guide of what is going to work for you. Shall we look at some of the options together? What might work for you?”

Care should be taken to offer support and information without falling into the ‘expert problem-solver trap’.

See Appendix 2 for guidelines when helping with decision making.

Phase 3: Follow-through Strategies

Reviewing Progress

Renewing Motivation

Redoing Commitment

NB Remember that in practical terms the outcome sought from Phase 3 is to ensure that the plan of action has been undertaken.

3.4 Therapy Rules

The Brief Treatment Programme is a scientific research study. As such it is vital that the therapy provided to patients in the study is not only of a high professional standard but that it is conducted under strictly controlled and consistent conditions. The rules below have been kept to a necessary minimum. Therapists must diligently endeavour to adhere to the rules and report any significant deviations if, and when, they occur.

3.4.1 *General MET rules for the Brief Treatment Programme*

The therapist must adhere to the treatment protocol.

MET is four sessions over six weeks. Try to schedule the four sessions at 1, 2, 4 and 6 weeks respectively.

Sessions last 40 minutes.

All sessions will be audiotaped.

Minimize interruptions during sessions. Use a DO NOT DISTURB sign on your door and call-forward your phone.

The treatment is both general and specific. Tailor the general principles and techniques of the treatment to the specific individual who is your patient.

Always give an appointment card to your patient and write it in your diary.

Phone contact is allowed. Ring patient once they are half an hour late for any session. Allow patient or “significant other” to ring you between sessions, but keep calls brief.

3.4.2 *Specific therapist rules*

The therapist must adhere to the treatment protocol and to the specific objectives of each session.

The therapist must give 100% in all their contacts with all patients in this study.

The therapist must actively involve themselves in the formal supervision sessions as well as between sessions where necessary.

If the therapist has an idea about the study, write it down and present it at your next meeting with the investigator.

Try and anticipate problems with each patient and seek guidance before they happen.

If you have any concerns about a patient, particularly their health, suicidality or violence, raise the issue immediately with all relevant people (e.g. Consultant Physician, Clinical Psychologist, GP and the investigator) according to usual practice standards.

3.5 The first session

3.5.1 *Introduction*

The MET approach may be surprising for some patients, who come with an expectation of being led step by step through an intensive process of therapist-directed change. For this reason, you must be prepared to give a clear and persuasive explanation of the rationale for this approach. The timing of this rationale is a matter for the therapist’s own judgement. It may not be necessary at the outset of MET. At least some structuring of what to expect, however, should be given to the patient at the beginning of the first session.

The following standard introduction is to be used for the start of the first session.

“Before we begin, I’d like to briefly explain the way we will be working together over the next six weeks.

This is the first of our sessions each of which will last about 40 minutes.

During these sessions we will be taking a close look at your diabetes together and I will be helping you to understand how you think and feel about your situation.

I want you to know I will not be trying to change you or your management of your diabetes; only you can do that. I may give you some advice along the way, but what you do with it will be completely up to you.

Do you have any questions before we begin?

Perhaps we could start by you updating me about how you see your situation now in terms of your diabetes?”

Many patients find MET a very comfortable approach. Some in fact will express relief, having feared being castigated or coerced. Others, however, may be uneasy with this approach and may need additional explanation and assurance. Several lines of follow-up discussion can include:

“Even with very extensive kinds of treatment, it is still the person who, in the end, decides what happens. You will determine what happens with your diabetes management.”

“Longer and shorter treatment programmes don’t seem to produce different results. People in longer or more intensive programmes don’t do any better, overall, than those getting good consultation like this. Again, no one can “do it to you”. In fact, many people change their behaviour without any formal treatment at all.”

“You are not alone. We will be keeping in touch with you to see how you are doing. If at follow-up visits, you still need more help, this can be arranged.”

“You can call if you need to. I’m available here by telephone.”

“I understand your worries, and it’s perfectly understandable that you would be unsure at this point. Let’s just get started, and we’ll see where we are after we’ve had a chance to work together.”

3.5.2 *Getting Underway*

Remember MET is therapist-directed; you call the shots. After the introduction, proceed by asking the patient to “put you in the picture” as best as they can by describing how they now see their situation. This can involve asking them to go over the main points of their diabetes history as well as inviting them to comment on what they thought of their recent appointment with their General Practitioner or Diabetes Consultant, and what (if anything) they have done since assessment. Respond to the patient’s comments with strategies for Eliciting Self-Motivational Statements (2.1.1). Use reflection Listening with Empathy (2.1.2) as your primary response during this early phase. Other strategies described under Questioning (2.1.3), Presenting Personal Feedback (2.1.4), Affirming the Patient (2.1.5), Handling Resistance (2.1.6) and Reframing (2.1.7) are also appropriate here.

If the patient is not particularly forthcoming or dries up quickly, then ask them to describe a typical day to get the ball rolling. Continue until you have elicited the major themes of concern from the patient and then offer a summary statement, see Summarizing (2.1.8).

If the patient does not seem to be expressing major concern about their diabetes and/or beginning to talk about their desire to change, then utilize some or all of the Phase 1 strategies: (ii) AGENDA SETTING (iii) PERSONAL DISSONANCE, (iv) GOOD THINGS – LESS GOOD THINGS, in order to build motivation for change (see p. 14-15). These strategies can also be used for patients who initially show some motivation for change but for whom further building up of motivation is judged to be appropriate.

Continue to focus on eliciting self-motivational statements during this process, drawing attention to them as they arise and noting them down. When you sense that genuine concern is being expressed by the patient about their management of their diabetes and the consequences associated with it as well as the desire to change then offer a summary statement; see Summarizing (2.1.8). This is the transition point to the second phase of MET: consolidating commitment to change. You may not get this far in the first session.

If there is time, continue the therapy process by using cues from the patient (see Recognizing Change Readiness 2.2.1) to elicit thoughts, ideas and plans for what might be done to address the problem (see Discussing a Plan 2.2.2). During this phase, also use procedures outlined under Communicating Free Choice (2.2.3), Information and Advice (2.2.5), and Dealing with Resistance (2.2.6) when necessary. Specifically elicit from the patient what are perceived to be the possible benefits of action and the likely negative consequences of inaction; see Consequences of Action and Inaction (2.2.4). Use the Phase 2 strategies outlined, (v) PROBLEMS AND CONCERNS, (vi) LIFE SATISFACTION, (vii) COSTS AND BENEFITS, (viii) CONSTRUCTING A DECISIONAL BALANCE and (ix) HELPING WITH DECISION MAKING (see p. 15-17).

The goal nominated by the patient should be included in discussion in this phase at an appropriate time.

The basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly is to be maintained throughout this and all MET sessions.

This phase proceeds toward the confirmation of a plan for change and the therapist should seek to obtain whatever commitment they can in this regard (see Asking for Commitment (2.2.9)). It can be helpful to write down the patient's goals and planned steps for change on the Change Plan Worksheet (2.2.7), a copy of which should be provided to the patient at the end of the session. If appropriate, this plan can be signed by the patient. The therapist, however, needs to be careful not to press prematurely for a commitment. If a plan is signed before commitment is firm, a patient may drop out of treatment rather than renege on the agreement.

3.5.3 Ending the Session

Always end the first session by summarizing what has transpired. The content of this summary will depend upon how far you have proceeded. In some cases, progress will be slow, and you will spend most of the first session presenting feedback and dealing with concerns or resistance. In other cases, the patient will be well along toward determination and you may be into Phase 2 (strengthening commitment) strategies by the end of the first session. The speed with which this session proceeds will depend upon the patient's current stage of change. Where possible, it is desirable to elicit some self-motivational statements from the patient about change within the first session and to take some steps toward discussing a plan for change (even if tentative and incomplete). Also discuss what the patient will do and what changes will be made (if any) between the first and second sessions. Do not hesitate to move toward commitment to change in the first session if this seems appropriate. On the other hand do not feel pressured to do so. Premature commitment is ephemeral and pressuring patients toward change before they are ready will evoke resistance and undermine the MET process.

3.5.4 The Follow-up Note

After the first session, prepare a handwritten note to be mailed to the patient. This is not a form letter, but rather a personalized message in your own (neat) handwriting. Several personalized elements can be included in this note including a "joining message", affirmations

of the patient, a reflection of the seriousness of the problem, a brief summary of the highlights of the first session, especially self-motivational statements that emerged, a statement of optimism and hope, and a reminder of the next session. An example might be as follows:

“Dear Mr Smith

This is just a short note following our first session today. I agree with you that there are some serious concerns for you to deal with, and I'm impressed at how openly you are exploring these. You are already seeing some of the ways in which you might make a healthy change and I think you're going to find a way through these problems. I look forward very much to meeting with you again on Monday 24 at 2pm.”

3.5.5 Checklist for Session 1

1. Check patient is to receive MET.
2. PLEASE DO NOT DISTURB sign, call-forward phone.
3. Check the tape-recorder is on and tape in.
4. Give an introduction and check that patient understands the MET rationale.
5. **Begin Phase 1 Building Motivation for Change.**
Invite patient to give an updated overview of their situation and elicit self-motivational statements, listen with empathy and affirm the patient as you go, handling resistance, reframing as appropriate and utilizing summaries.
6. If appropriate, use the Phase 1 strategies.
7. Make a final summarizing statement.
8. **Move on to Phase 2 Strengthening Commitment to Change – if time.**
Use cues to recognize change readiness and then begin to discuss a plan for change, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
9. If appropriate, use the Phase 2 strategies.
10. End session with a summarizing statement.
11. Give patient copy of decision balance sheet and/or change plan worksheet if completed.
12. Give patient appointment card for Session 2 in a week's time and write it in your diary.
13. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room before leaving.
14. Complete staff version of Goals for Change Checklist and Readiness to Change Ruler.
15. Write and post follow-up note immediately following the session.

3.6 The Second Session

The second session is scheduled a week after the first session and should begin with a brief summary of what transpired during the first session. Then proceed with the MET process, picking up where you left off. Continue with personal feedback from assessment if this was not completed during the first session. Proceed toward Phase 2 strategies and commitment to change if this was not completed in the first session. If a firm commitment was obtained in the first session, then proceed with follow-through procedures.

At the end of the second session, in all cases, offer a closing summary of the patient's reasons for concern, the main themes of the feedback, and the plan that has been negotiated, see Recapitulation (2.2.8). This marks the closing of the second session.

If no commitment to change has been made, indicate that you will see how the patient is doing at the next session in two weeks time and will continue discussion at that point. In any event, remind the patient of the third session in two weeks time.

3.6.1 Checklist for Session 2

1. Check patient is receiving MET.
2. PLEASE DO NOT DISTURB sign, call-forward phone.
3. Check the tape-recorder is on and tape in.
4. Give a brief summary of first session.
5. Continue towards completion of Phase 2 Strengthening Commitment to Change. Use cues to recognize change readiness and continue discussion of a plan for change, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
6. If appropriate, use the Phase 2 strategies.
7. Complete the Change Plan Worksheet and if appropriate sign it.
8. Offer a closing summary (patient's reasons for concern, main themes of the feedback, and negotiated plan).
9. Give patient copy of decision balance sheet and/or change Plan Worksheet if completed.
10. Give patient appointment card for session 3 in two weeks time and write it in your diary.
11. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room before leaving.
12. Complete staff versions of Goals for Change Checklist and Readiness to Change Ruler.

3.7 The Third and Fourth Sessions

Sessions three and four are to be scheduled for weeks 4 and 6 respectively. They are important as “booster” sessions to reinforce the motivational processes begun in the initial sessions. As before, the therapist does not offer skill training or prescribe a specific course of action unless requested to do so by the patient. Rather, the same motivational principles are applied throughout MET. Specific use is made in each session of the follow-through-strategies outlined earlier:

- (1) reviewing progress
- (2) renewing motivation
- (3) redoing commitment

Begin each session with a discussion of what has transpired since the last session and a review of what has been accomplished in previous sessions. Complete each session with a summary of where the patient is at present, eliciting the patient's perceptions of what steps should be taken next. The prior plan for change can be reviewed, revised and (if previously written down) rewritten.

During these sessions, the therapist needs to be careful not to assume that ambivalence has been resolved and commitment is firm. It is safer to assume that the patient is still ambivalent and to continue using the motivation-building strategies of Phase 1 as well as the commitment-strengthening strategies of Phase 2.

There should be a clear sense of continuity of care. The four sessions of MET should be presented as progressive consultations, so that the initial session build motivation and strengthen commitment and the subsequent sessions serve as periodic checkups of progress toward change. It can be helpful during sessions 3 and 4 to discuss situations, which have occurred when the patient's goal was broken or threatened.

If the goal was broken, discuss how it occurred. It is important for the therapist to remain empathic and to avoid a judgmental tone or stance. Consistent with the MET style, the therapist must not prescribe coping strategies for the patient. Rather, the discussion should be used to review the goal, renew motivation, eliciting from the patient further self-motivational statements by asking for the patient's thoughts, feelings, reactions and realizations. Key questions can be used to renew commitment such as, “So what does this mean for the future?” or “I wonder what you will need to do differently next time?”

Patients may also find it helpful and rewarding to review situations in which they managed their diabetes well previously. Reinforce self-efficacy by asking patients to clarify what they did to cope successfully in these situations. Therapists should praise patients for small steps, little successes, even minor progress.

3.7.1 Checklist for Session 3

1. Check patient is receiving MET.
2. PLEASE DO NOT DISTURB sign, call-forward phone.
3. Check the tape-recorder is on and tape in.
4. Give a brief summary of Session 2 based on the closing summary (patient's reasons for concern, main themes of the feedback, and negotiated plan).
5. Review progress, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
6. If appropriate, facilitate renewing motivation and/or redoing commitment.
7. If appropriate, discuss situations where patient's goal was broken or threatened, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
8. End session with a summarizing statement.
9. Give patient copy of Decision Balance Sheet and/or Change Plan Worksheet if completed.
10. Give patient appointment card for Session 4 in two weeks' time and write it in your diary.
11. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room before leaving.
12. Complete staff versions of Goals for Change Checklist and Readiness to Change Ruler.

3.8 Termination

Formal termination should be acknowledged and discussed at the end of the fourth session. This is generally accomplished by a final recapitulation of the patient's situation and progress through the MET sessions. The final summary should include the following elements:

- Review the most important factors motivating the patient for change and reconfirm these self-motivational themes.
- Summarize the commitments and changes that have been made thus far.
- Affirm and reinforce the patient for commitments and changes that have been done.
- Explore additional areas for change that the patient wants to accomplish in the future.
- Elicit self-motivational statements for the maintenance of change and for further change.
- Support patient self-efficacy, emphasizing the patient's ability to change.
- Deal with any special problems that are evident (see below).
- Remind the patient of the follow-up sessions at 3 and 6 months, following the final session and their usual clinic follow-up 12-15 months since their last appointment with the consultant physician.

Review in the final session the major points that have come up in the prior three sessions. It may be useful to ask patients about the worst things that could happen if they went back to managing their diabetes as before. Help patients look to the immediate future, to anticipate upcoming events or potential obstacles to continuing with their goal of improved diabetes management.

3.8.1 *Checklist for Session 4*

1. Check patient is receiving MET.
2. PLEASE DO NOT DISTURB sign, call-forward phone.
3. Check the tape-recorder is on and tape in.
4. Give a brief summary of session 3, based on the closing summary of session 2 (patient's reasons for concern, main themes of the feedback, and negotiated plan) with any modifications from session 3.
5. Review progress, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
6. If appropriate, facilitate a renewing motivation and/or redoing commitment.
7. If appropriate, discuss situations where patient's goal was broken or threatened, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
8. Termination consisting of a final recapitulation of the patient's situation and progress through the four MET sessions.
9. Give patient copy of Decision Balance Sheet and/or Change Plan Worksheet if completed.
10. Give patient Goals for Change Checklist, Readiness to Change Ruler, and Post-treatment questionnaires (4) to complete in waiting room before leaving.
11. Weigh patient and give form for blood test (HbA_{1c}, lipids).

4. DEALING WITH SPECIAL PROBLEMS

Special problems can arise during any treatment. Below are general trouble-shooting procedures for handling four situations that may arise.

4.1 Treatment Dissatisfaction

Patients may report thinking that the assigned treatment is not going to help or wanting a different one. Under these circumstances, you should first reinforce patients for being honest about their feelings. You should also confirm that they have the right to withdraw from the study, stop treatment at any time, seek help elsewhere or decide to work on the problem on their own.

Concerns of this kind that arise during the first session are probably reservations about an approach they have not yet tried. It is appropriate to assure the patient that the treatments in the study are expected to be successful and that the therapist will be offering all the help they can. No one can guarantee that any particular treatment will work, but you can encourage the patient to give it a good try for the planned period and see what happens. You can add that should the problem continue or worsen, you will discuss other possible approaches.

If a patient expresses reservations after two or three sessions, consider whether there have been new developments. Have new problems arisen? Did the plan for change that was previously developed with the patient fail to work, and if so, why? Was it properly implemented? Was it tried for long enough? Is there input or pressure from someone else for a change in approach or for discontinuation of treatment? Is the patient discouraged?

If the patient's diabetes management has shown improvement but new problems, not previously identified, have appeared, these new problems can be discussed following (and not departing from) the treatment procedures outlined above. The discussion of new problems and concerns, or a review of how prior implementation failed, can set the stage for continuation of treatment. You can suggest that it may be too early to judge how well this approach will work and that the patient should continue the therapy over the six week period as arranged. After that, if the patient still feels a need for additional treatment, he or she could certainly obtain it. If other parties are concerned about this treatment and are pressuring the patient, you can explore this problem by following the treatment guidelines outlined above. It is also permissible for the therapist to telephone the concerned party (with written consent from the patient) to discuss the concerns and provide assurances, along the same lines as those outlined above for similar patient concerns.

In the Brief Treatment Programme, a limit of no more than two additional "emergency" MET sessions may be provided at the therapist's discretion. These must remain consistent with the MET guidelines as described above and can be viewed as an extension or intensification of MET. All sessions, including any emergency sessions, must be completed within six weeks of the first session. After that date, therapists are no longer permitted to see the patient for any session, even if MET has not been completed. In the event of patients wanting further help, beyond that provided in the Brief Treatment Programme, despite attempts to retain them within the research protocol, referral to an outside agency or to another Diabetes Centre staff member, who is not involved in the Brief Treatment Programme, should be actively facilitated.

4.2 Missed Appointments

When a patient misses a scheduled appointment, respond immediately. First try to reach the patient by telephone, once the patient is half an hour late, and when you do, cover these points:

- Clarify the reasons for the missed appointment.
- Affirm the patient – reinforce, for coming in the first instance.
- Express your eagerness to see the patient again.
- Briefly mention serious concerns that emerged and your appreciation (as appropriate) that the patient is exploring these.
- Express your optimism about the prospects for change.
- Reschedule the appointment.

If no reasonable explanation is offered for the missed appointment (e.g. illness, transportation breakdown) explore with the patient whether the missed appointment might reflect any of the following:

- Uncertainty about whether or not treatment is needed
- Ambivalence about making a change

Handle such concerns in a manner consistent with MET (e.g. with reflective listening, reframing). Indicate that it is not surprising in the beginning phase of consultation for people to express their reluctance by not showing up for appointments, being late etc. Encouraging the patient to voice these concerns directly may help to reduce their expression in future missed appointments. Use Phase 1 strategies to handle any resistance that is encountered. Affirm the client for being willing to discuss concerns. Then summarize what you have discussed, add your own optimism about the prospects for positive change, and obtain a recommitment to treatment. It may be useful to elicit some self-motivational statements from the patient in this regard. Reschedule the appointment.

In all cases, unless you regard it as a duplication of the telephone contact that might offend the patient, also send a personal, individualized (neatly) handwritten note with the essential points. This should be done within two days of the missed appointment. Place a copy of this note in the clinical file. This procedure should be used when any of the four appointments are missed. Three attempts (new appointments) should be made to reschedule a missed session.

4.3 Telephone Consultation

Some patients and their significant others may contact you by telephone between sessions for additional consultation. This is acceptable and all such contacts should be carefully documented in the patient's file. An attempt should be made to keep such contacts brief, rather than providing additional sessions by telephone. All telephone contacts must also comply with the basic procedures of MET. Specific change strategies should not be prescribed, unless specifically requested. Rather, your approach emphasizes elicitation and reflection.

4.4 Crisis Intervention

If at any time, in the therapist's opinion, the immediate welfare and safety of the patient or another person is in jeopardy (e.g. health, suicidality, violence), the therapist must intervene immediately and appropriately for the protection of those involved, with appropriate consultation with other Diabetes Centre Staff and/or GP, and the investigator. In the Brief Treatment Programme, the therapist's involvement in crisis interventions cannot exceed two sessions above and beyond those prescribed by the treatment condition. If a patient's urgent needs require more additional treatment than this, referral is arranged.

APPENDIX A

- **Change Plan Worksheet**
- **Agenda Setting Chart**
- **Decision Balance Worksheet**

Participant#

Date

CHANGE PLAN WORKSHEET

Goals (changes I want to make)

Reason for change

Steps (how will I achieve the goals?)

Support (how others can help me)

Benefits (how will I know if it is working?)

Possible problems (what could interfere with my plan?)

Participant#

Date

DECISION BALANCE WORKSHEET

CONSEQUENCES		NO CHANGE	CHANGE
Positive	<i>Short term</i>		
	<i>Long term</i>		
Negative	<i>Short term</i>		
	<i>Long term</i>		
REASONS <i>(Importance 1-10)</i>			

APPENDIX B

- **Table 2: Presenting Personal Feedback.....**
- **Table 3: Problems and Concerns.....**
- **Table 4: Good things, less good things**
- **Table 5: Helping with decision-making**

Table 2: Presenting Personal Feedback

TECHNIQUE OUTLINE
<p>Aim</p> <p>To provide information about diabetes in a sensitive manner.</p> <p>How not to do it!</p> <p>The worst way to provide information is to “wag your finger” at the patient, for example <i>“You are.....and if you are not careful, you will.....and then you will find that.....”</i></p> <p>With a moralistic tone to your voice, you risk pushing the patient into a corner. They will have no choice but either to agree with you (or pretend to), or to disagree.</p> <p>How to do it</p> <ol style="list-style-type: none"> 1. Choose the right moment and ask permission. <ul style="list-style-type: none"> • Best when patient seems curious, actually asks for information, or is at least not in a defensive frame of mind. • Your voice tone should be neutral. If the patient decides not to receive information, that’s their choice. • Ask permission, for example: <i>“I wonder, would you be interested in knowing more about?”</i> 2. Provide information in a neutral and non-personal way, referring generally to “what happens to people” rather than to this particular person. Also useful to refer to what experts think, rather than yourself. 3. When finished, ask: <i>“I wonder, what do you make of all this? How does it tie in with your diabetes management?”</i> <p>Note</p> <ul style="list-style-type: none"> • Take your time when discussing the personal implications in Step 3 above. • Some people don’t need or want information: because they already know the facts, or because they are not ready to receive them. That’s why it’s important to ask permission and gauge their reaction first. • Giving people potentially “frightening” information does not necessarily motivate them to change. It can have the opposite effect.

Table 3: Problems and Concerns

STRATEGY OUTLINE
<p>Aim</p> <p>To help patients express for themselves what concerns they have about their diabetes.</p> <p>Functions</p> <p>This is a key strategy, often the foundation for building motivation. It highlights elements of the ambivalence conflict, and can lead to the generation of discrepancy – a sense of discomfort – which often precedes the decision to make a change. It can only be used with patients who are concerned about their behaviour.</p> <p>What to do</p> <ol style="list-style-type: none"> 1. Ask the key question: <i>“What concerns to you have about your diabetes/diabetes management?”</i> <ul style="list-style-type: none"> • Explore in detail whatever concern is raised. (If more than one concern is raised simultaneously, take them one at a time). Use open questions and reflective listening. • Summarize this concern (in “you” language). Highlight contrast with the “good things” about diabetes for this person. 2. Ask: <i>“What other concerns do you have about your diabetes/diabetes management?”</i> <ul style="list-style-type: none"> • Explore in detail, as above. • Summarize both this and the first concern, and highlight the “good things” as well (if appropriate). 3. Ask: <i>“What else, what other concerns do you have....?”</i> <ul style="list-style-type: none"> • Explore, as above. • Having covered all concerns, summarize them and highlight contrast with good things about diabetes. <p>Reminders</p> <ul style="list-style-type: none"> • Don’t rush. Use simple open questions to encourage patient: e.g. <i>“Why does this concern you?”</i>, <i>“Can you give me an example?”</i>, <i>“What concerns you the most about this?”</i> • Don’t move too far away from exploring concerns. • Highlighting discrepancy, often most evident after using this strategy, can lead to discomfort. Be supportive, and don’t rush the person into a decision to change. Let them raise this topic.

Table 4: Good things, less good things

STRATEGY OUTLINE
<p>Aim</p> <p>To explore patients' feelings about the behaviour in question, without imposing on them any assumptions about it being problematic. They, rather than you, identify problem areas or reasons for concern.</p> <p>Functions</p> <p>Often used soon after first raising the subject, this strategy serves the following functions.</p> <ol style="list-style-type: none"> 1. Useful for building rapport, and for understanding context of substance use. 2. Useful with patients who seem unconcerned, or when you are unsure about what they feel about their diabetes management. Resistance is minimised because: <ul style="list-style-type: none"> • You start with the positive things about person's diabetes management. • You talk about "less good things" rather than "concerns". This allows the patient to identify problem areas without feeling that these are being labelled as problematic. <p>How to do it</p> <ol style="list-style-type: none"> 1. Ask the key question: <i>"What are some of the good things about your diabetes/diabetes management?"</i> These usually emerge quite quickly. Summarize them, if necessary. 2. Ask: <i>"What are some of the less good things about your diabetes/diabetes management?"</i> Elicit these one by one, with the aim of finding out why this patient thinks these are "less good things." Open questions are useful here, for example, "How does this affect you" or "What don't you like about it?" 3. Summarize the good things and the less good things, in "you" language, as succinctly as possible, and leave the person time to react. For example: <i>"So managing your diabetes can be a hassle, especially taking regular blood sugar tests and eating regularly. On the other hand, you say you feel so much better, you have more energy when you do, and since you have made changes to your eating you have been feeling much healthier"</i>. <p>Note</p> <ul style="list-style-type: none"> • Avoid using words like "problem" or "concern" unless the patient does. If this happens, consider moving soon on to the "Problems and Concerns" strategy. Don't assume that "a less good thing" is a cause for a concern to patient. • Keep to task at hand, and avoid raising new topics or hypothesis of your own. • An alternative format is to ask, "What do you <i>like/dislike</i> about your diabetes?"

Table 5: Helping with decision-making

GUIDELINES
<ul style="list-style-type: none">• Do not rush patients into decision-making.• Present options for the future rather than a single course of action.• Describe what other patients have done in a similar situation.• Emphasise that “you are the best judge of what will be best for you.”• Provide information in a neutral non-personal manner.• Failure to reach a decision to change is not a failed consultation.• Resolutions to change often break down. Make sure that patients understand this and do not avoid future contact if things go wrong.• Commitment to change is likely to fluctuate. Expect this to happen and empathise with the patient's predicament.

APPENDIX C

MET Session Checklists

- **Session 1**
- **Session 2**
- **Session 3**
- **Session 4**

MET Session Checklists

Checklist for Session 1

1. Check patient is to receive MET.
2. Collect completed SOCRATES from patient.
3. PLEASE DO NOT DISTURB sign, call-forward phone.
4. Check the tape-recorder and microphone is on, and tape in.
5. Give an introduction and check that patient understands the MET rationale.
6. **Begin Phase 1 Building Motivation for Change.**
Invite patient to give an updated overview of their situation and elicit self-motivational statements, listen with empathy and affirm the patient as you go, handling resistance, reframing as appropriate and utilizing summaries.
7. If appropriate, use the Phase 1 strategies.
8. Make a final summarizing statement.
9. **Move on to Phase 2 Strengthening Commitment to Change – if time.**
Use cues to recognize change readiness and then begin to discuss a plan for change, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
10. If appropriate, use the Phase 2 strategies.
11. End session with a summarizing statement.
12. Give patient copy of decision balance sheet and/or change plan worksheet if completed.
13. Give patient sufficient Food Record Sheets to keep a daily record until next session, with encouragement to keep recording.
14. Collect completed Food Record Sheets. Check patient number and dates are on these.
15. Give patient appointment card for Session 2 in a week's time.
16. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room, with instructions to place in envelope and leave with reception before leaving.
17. Complete staff version of Goals for Change Checklist and Readiness to Change Ruler.

18. Write and post follow-up note immediately following the session.
19. Put the following in Eileen's pigeon-hole: tape (labelled with patient number and date); envelope containing SOCRATES; Food Record Sheets, and staff version of GCC and RCR.

Checklist for Session 2

1. Check patient is receiving MET.
2. Collect completed SOCRATES.
3. PLEASE DO NOT DISTURB sign, call-forward phone.
4. Check the tape-recorder and microphone is on, and tape in.
5. Give a brief summary of first session.
6. Continue towards completion of Phase 2 Strengthening Commitment to Change. Use cues to recognize change readiness and continue discussion of a plan for change, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
7. If appropriate, use the Phase 2 strategies.
8. Complete the Change Plan Worksheet and if appropriate sign it.
9. Offer a closing summary (patient's reasons for concern, main themes of the feedback, and negotiated plan).
10. Give patient copy of decision balance sheet and/or change Plan Worksheet if completed.
11. Give patient sufficient Food Record Sheets to keep daily record until next session, with encouragement to keep recording.
12. Collect completed Food Record Sheets. Check patient number and dates are on these.
13. Give patient appointment card for session 3 in two weeks time.
14. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room before leaving, with instructions to place in envelope and leave with reception before leaving.
15. Complete staff version of Goals for Change Checklist and Readiness to Change Ruler
16. Put the following in Eileen's pigeon-hole: tape (labelled with patient number and date); envelope containing SOCRATES; Food Record Sheets, and staff version of GCC and RCR.

Checklist for Session 3

1. Check patient is receiving MET.
2. Collect completed SOCRATES.
3. PLEASE DO NOT DISTURB sign, call-forward phone.
4. Check the tape-recorder and microphone is on, and tape in.
5. Give a brief summary of Session 2 based on the closing summary (patient's reasons for concern, main themes of the feedback, and negotiated plan).
6. Review progress, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
7. If appropriate, facilitate renewing motivation and/or redoing commitment.
8. If appropriate, discuss situations where patient's goal was broken or threatened, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
9. End session with a summarizing statement.
10. Give patient copy of Decision Balance Sheet and/or Change Plan Worksheet if completed.
11. Give patient sufficient Food Record Sheets to keep a daily record until next session, with encouragement to keep recording.
12. Collect completed Food Record Sheets. Check patient number and dates are on these.
13. Give patient appointment card for Session 4 in two weeks' time.
14. Give patient Goals for Change Checklist and Readiness to Change Ruler to complete in waiting room, with instructions to place in envelope and leave with reception before leaving.
15. Complete staff version of Goals for Change Checklist and Readiness for change Ruler.
16. Put the following in Eileen's pigeon-hole: tape (labelled with patient number and date); envelope containing SOCRATES; Food Record Sheets, and staff version of GCC and RCR.

Checklist for Session 4

1. Check patient is receiving MET.
2. Collect completed SOCRATES.
3. PLEASE DO NOT DISTURB sign, call-forward phone.
4. Check the tape-recorder and microphone is on, and tape in.
5. Give a brief summary of session 3, based on the closing summary of session 2 (patient's reasons for concern, main themes of the feedback, and negotiated plan) with any modifications from session 3.
6. Review progress, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
7. If appropriate, facilitate a renewing motivation and/or redoing commitment.
8. If appropriate, discuss situations where patient's goal was broken or threatened, maintaining the basic stance of reflection, questioning, affirming, reframing and dealing with resistance indirectly, throughout.
9. Termination consisting of a final summary of the patient's situation and progress through the four MET sessions.
10. Give patient copy of Decision Balance Sheet and/or Change Plan Worksheet if completed.
11. Give patient sufficient Food Record Sheets to keep daily record until two week follow-up, with encouragement to keep recording.
12. Collect completed Food Record Sheets. Check patient number and dates are on these.
13. Remind patient of post-treatment assessment in two weeks with Eileen (Eileen will contact to make a time).
14. Weigh patient and give form for blood test (fasting HbA1c, lipids)
15. Give patient Goals for Change Checklist and Readiness to Change Ruler, to complete in waiting room, with instructions to place in envelope and leave with reception before leaving.
16. Complete staff version of Goals for Change Checklist and Readiness for Change Ruler.

17. Put the following in Eileen's pigeon-hole: tape (labelled with patient number and date); envelope containing SOCRATES; Food Record Sheets, and staff version of GCC and RCR
18. Notify Eileen that MET has been completed and leave research folder for Eileen to collect.

Appendix 3: Evaluating statistical difference, equivalence, and indeterminacy using inferential confidence intervals
(Tryon, 2001)

Statistical Difference

Two Independent Means

A reduced inferential CI about each mean is constructed so that non-overlap equates to statistical difference by a standard t test:

$$\bar{Y} \pm E t_{\alpha/2} S_{\bar{Y}} = \bar{Y} \pm E t_{\alpha/2} \frac{S}{\sqrt{N}}$$

E is defined as the ratio of the standard error of the difference between two groups to the sum of the standard errors of both groups:

$$t_x = t_{95} \frac{\sqrt{S_{\bar{Y}_1}^2 + S_{\bar{Y}_2}^2}}{S_{\bar{Y}_1} + S_{\bar{Y}_2}} = t_{95} E$$

The first step is to establish the level of statistical significance to determine how to calculate descriptive CIs about each mean. In this case it is set at 5% level of statistical significance for 95% confidence.

The next step is to calculate E , the extent to which the descriptive CI must be reduced to obtain an inferential CI on the basis of the experimental design used.

e.g.
$$E = \frac{\sqrt{(2.6920)^2 + (0.7054)^2}}{2.6920 + 0.7054} = .8191$$

The inferential CI is 81.91% as large as the descriptive CI.

The next step is to calculate the critical t value for $df = N - 1$

e.g. $N=20$, $df=N-1=19$ at the 5% significance (95% confidence) level $t=2.0930$.

The inferential CI is then constructed using a proportionately reduced critical t value.

The reduced t value is:

$$t_x = .8191 (2.0930) = 1.7144$$

The resulting inferential CIs for each of the two groups are as follows:

Group A: $68 \pm 1.7144 (2.6920) = 63.385$ to 72.615

Group B: $75 \pm 1.7144 (0.7054) = 73.791$ to 76.209

Statistical difference is said to exist between the two groups because the two inferential CIs do not overlap; the upper limit of the lesser mean (72.615) is less than the lower limit of the greater mean (73.791). The probability value associated with this statistical difference is $p < .05$ because the critical value for the 5% significance level (95% confidence level) was the initial t value.

Two Dependent Means

The previous analysis for two independent means can be extended to two dependent means of equal or unequal sample sizes. The E term has the same meaning as above. The only difference is the presence of a term that is twice the correlation between the two variables multiplied by the standard errors of each variable. The correlation between the two variables further reduces E below what is possible in the independent-groups design, thereby further narrowing the inferential CIs about each mean:

$$t_x = t_{95} \frac{\sqrt{S \frac{2}{Y_1} + S \frac{2}{Y_2} - 2 r_{12} S_{\bar{Y}_1} S_{\bar{Y}_2}}}{S_{\bar{Y}_1} + S_{\bar{Y}_2}} = E t_{95}$$

e.g. $E = \frac{\sqrt{(1.1916)^2 + (1.2552)^2 - 2(0.521)(1.1916)(1.2552)}}{1.1916 + 1.2552} = .4899$

The critical t value for $N = 20$, $df = 19$, at the 5% significance level is 2.0930.

This results in a value of:

$$t_x = .4899 (2.0930) = 1.0254$$

and the following two inferential CIs:

Group E: $50 \pm 1.0254 (1.1916) = 48.778$ to 51.222

Group F: $54 \pm 1.0254 (1.2552) = 52.713$ to 55.287

Evidence of statistical difference exists because these two inferential CIs do not overlap. Again, the p value associated with this statistical difference is .05 because the critical t value was set at the 5% significance level before multiplying by E .

Statistical Equivalence

The first step is to specify the maximum amount of difference (R_g) that one is willing to ignore in the name of equivalence on substantive grounds. For illustrative purposes, $\Delta = 3.0$. This means that the difference between the lower limit of the lesser mean and the upper limit of the greater mean must be less than or equal to 3.0 for statistical equivalence to exist.

The standard errors for each group are obtained by dividing the standard deviation of each group by the square root of the number of subjects in each group.

$$\text{e.g. } E = \frac{\sqrt{(0.7054)^2 + (0.5293)^2}}{0.7054 + 0.5293} = .7143$$

The equal sample size of 20 subjects resulting in 19 degrees of freedom is associated with a 5% critical t value of 2.0930. This results in:

$$t_x = .7143 (2.0930) = 1.4950$$

and the following inferential CIs:

$$\text{Group B: } 75 \pm 1.4950 (0.7054) = 73.945 \text{ to } 76.055$$

$$\text{Group C: } 76 \pm 1.4950 (0.5293) = 75.209 \text{ to } 76.791$$

The difference between the lower limit of the lesser mean of 73.945 and the upper limit of the greater mean of 76.791 is $R_g = 2.846$, which is less than the stipulated Delta value of 3.0, and therefore we conclude that the means of these two groups are statistically equivalent.

The p value for this statement is .05 because the critical value associated with the 5% significance level was initially chosen before being reduced by the E factor to obtain the inferential CI.

Appendix 4: Goals for change checklists

Participant#.....

Date.....

Goals for Change Checklist: Participant

Please indicate (by putting a tick in the space provided) which of the following you consider to be the main goal(s) you have as a result of your last appointment. Do not indicate more than two goals. If you have more than two goals, indicate the two goals you consider to be most important.

- ☐ **No change – stay same**
- ☐ **Change foot wear**
- ☐ **Decrease exercise/activity**
- ☐ **Increase exercise**
- ☐ **Take medication as instructed**
- ☐ **Record medication use**
- ☐ **Test blood sugars regularly**
- ☐ **Record blood sugars**
- ☐ **Eat more healthily**
- ☐ **Eat more regularly**
- ☐ **Record food intake**
- ☐ **Lose weight**
- ☐ **Decrease alcohol intake**
- ☐ **Stop smoking**
- ☐ **Other – please specify**
- ☐ **Other – please specify**

Staff name:

Date.....

Participant#:.....

Goals for Change Checklist: Staff

Please indicate (by putting a tick in the space provided) which of the following you consider to be the main goal(s) resulting from your last appointment. Do not indicate more than two goals. If there are more than two goals, indicate the two goals you consider to be most important.

- ☐ **No change – stay same**
- ☐ **Change foot wear**
- ☐ **Decrease exercise/activity**
- ☐ **Increase exercise**
- ☐ **Take medication as instructed**
- ☐ **Record medication use**
- ☐ **Test blood sugars regularly**
- ☐ **Record blood sugars**
- ☐ **Eat more healthily**
- ☐ **Eat more regularly**
- ☐ **Record food intake**
- ☐ **Lose weight**
- ☐ **Decrease alcohol intake**
- ☐ **Stop smoking**
- ☐ **Other – please specify**
- ☐ **Other – please specify**

Appendix 5: Treatment Evaluation Inventory (modified)

Participant #

Date

Please complete the items listed below. The items should be completed by placing a checkmark on the line under the question that best indicates how you feel about the treatment. Please read the items very carefully because a checkmark accidentally placed on one space rather than another may not represent the meaning you intended.

1. How acceptable to you find this treatment?

_____	_____	_____	_____	_____	_____	_____
not at all acceptable			moderately acceptable			very acceptable

2. How consistent is this treatment with common sense or everyday notions about what treatment should be?

_____	_____	_____	_____	_____	_____	_____
very different or inconsistent			moderately consistent			very consistent with everyday notions

3. To what extent does this procedure treat you humanely?

_____	_____	_____	_____	_____	_____	_____
does not treat humanely at all			treats me moderately humanely			treats me very humanely

4. To what extent do you think there might be risks in undergoing this kind of treatment?

_____	_____	_____	_____	_____	_____	_____
lot of risks are likely			some risks are likely			no risks are likely

5. How much do you like the procedures used in this treatment?

do not like them at all moderately like them like them very much

6. How effective is this treatment likely to be?

not at all effective moderately effective very effective

7. How likely is this treatment to help you make permanent improvements?

unlikely moderately likely very likely

8. To what extent are undesirable side effects likely to result from this treatment?

many undesirable
side effects
likely

some undesirable
side effects
likely

no undesirable
side effects
would occur

9. How much discomfort did you experience during the course of treatment?

very much discomfort moderate discomfort no discomfort at all

10. Overall, what is your general reaction to this form of treatment?

Appendix 6: Calculating of Reliable Change Index (Truax, 1991)

$$RC = \frac{\chi_2 - \chi_1}{S_{\text{diff}}}$$

Where χ_1 represents a subject's pre-test score, χ_2 represents that same subject's post-test score, and S_{diff} is the standard error of difference between the two test scores. S_{diff} can be computed directly from the standard error of measurement S_E according to this:

$$S_{\text{diff}} = \sqrt{2(S_E)^2}$$

S_{diff} describes the spread of the distribution of change scores that would be expected if no actual change had occurred. An RC larger than 1.96 would be unlikely to occur ($p < .05$) without actual change.

Appendix 7: Description of Study 2 Participants

PE and MET participants had similar reasons for referral to the dietitian (Table 43), with assistance with diabetes management the main reason for referral. Problems with diet and/or weight were specifically mentioned for most participants (n=4 for PE and MET), with poor diabetes control specifically mentioned as a problem for two PE participants. All participants (i.e. PE and MET) were referred by their GP (Table 43).

Table 43: Summary of referral information

	PE	MET
Reason		
Assistance with diabetes management	5	5
Poor diabetes control	2	0
Diet / weight problems	4	4
Source		
GP	6	5
Diabetes physician	0	0

Only one participant (a PE participant) experienced diabetes-related complications (Table 44). This is consistent with the relatively short duration (i.e., PE n=4.6, MET n=6.8) since diagnosis of their diabetes.

Table 44. Diabetes complications experienced by Participants

Complications	PE	MET
Nil	5	5
Infections	1	0

PE and MET participants were also fairly similar in the other health problems experienced, with about half (i.e., PE n=3, MET n=2) of participants not experiencing any other health problems in addition to diabetes (Table 45). Only one participant (a MET participant) experienced multiple health problems (i.e. had more than one health problem in addition to diabetes).

Table 45. Other health problems experienced by participants

Health problem	PE	MET
Hearth disease	2	0
Chronic pain	1	1
Psychiatric disorder	0	1
Asthma	0	2
Nil	3	4

Most participants were prescribed oral medication for their diabetes (Table 46). No participants were prescribed insulin for their diabetes and some participants (i.e., PE n=1, MET n=2) were not prescribed any medication for their diabetes. This is consistent with their relatively short duration of diagnosis of Type 2 diabetes combined with the lack of diabetes-related complications. Only two participants (both PE participants) were prescribed lipid lowering medication.

Table 46. Summary of participants' medication

Medication	PE	MET
Oral diabetes	5	3
Insulin	0	0
Lipid lowering	2	0
Antihypertensive	2	1
Other	2	2
Nil	0	0

PE and MET participants were similar in their employment status (Table 47), with only one participant in each group in receipt of welfare assistance due to illness. Participants were engaged in a range of work, with manual work the most common (i.e., n=2 for both PE and MET).

Table 47. Employment status of participants

Employment	PE	MET
Manual	2	2
Office	1	0
Business	0	1
Tertiary student	0	1
Retired	2	0
Sickness beneficiary	1	1

Case Descriptions

Case 19. A 59 year old Maori male with Type 2 diabetes diagnosed at 48 years of age. He was described as having minimal tinea (fungal skin infection) which was attributed to his diabetes. At baseline, he was also prescribed Bezalip for dyslipidaemia, which was altered to Simvastatin during PE (i.e., week 8). His diabetes medication remained unchanged throughout the study.

Case 20. A 69 year old Caucasian male with Type 2 diabetes diagnosed at 68 years of age. He had no known diabetes-related complications. His diabetes was managed through diet and oral medication (Metformin). His diabetes medication remained unchanged throughout the study.

Case 21. A 55 year old Caucasian female with Type 2 diabetes diagnosed at 50 years of age. She had no known diabetes-related complications. At baseline, her diabetes was managed through diet and oral medication (Metformin and Glibenclamide). At 12-month follow-up, however, her diabetes medication had been altered to include insulin (Penmix) injections along with oral diabetes medication (Metformin only). Simvastatin for dyslipidaemia was also added at this time. She attended 10 further appointments (i.e. in addition to the PE sessions with the dietitian) at the Diabetes Centre (two each with a DNE, dietitian, podiatrist, and physician) over the course of follow-up.

Case 22. A 49 year old Caucasian female with Type 2 diabetes diagnosed at 41 years of age. She had no known diabetes-related complications. Her diabetes was managed through diet and oral medication (Metformin). Her diabetes medication remained unchanged throughout the study.

Case 23. A 38 year old Caucasian male with Type 2 diabetes diagnosed at 34 years of age. He had no known diabetes-related complications. His diabetes was managed through diet and oral medication (Metformin). His diabetes medication remained unchanged throughout the study. He attended two further appointments with a dietitian during follow-up.

Case 24. A 44 year old Caucasian female with Type 2 diabetes diagnosed at 43 years of age. She had no known diabetes-related complications. Her diabetes was managed through diet alone, which remained unchanged throughout the study.

Case 25. A 51 year old Caucasian male with Type 2 diabetes diagnosed at 46 years of age. He had no known diabetes-related complications. His diabetes was managed through diet and oral medication (Metformin). His diabetes medication remained unchanged throughout the study. Unfortunately, he was not able to be contacted for 12-month follow-up because of his work commitments consequently no 12-month follow-up data are available.

Case 26. A 63 year old Caucasian female with Type 2 diabetes diagnosed at 55 years of age. She had no known diabetes-related complications. At baseline, her diabetes was managed through diet and oral medication (Metformin). Her diabetes medication had been altered at 12-month follow-up to include Glipizide. Additionally, over the course of follow-up she was seen by a Clinical Psychologist for seven treatment sessions between 3- and 6-month follow-up focusing on her marital situation and binge eating. She also received four further dietetic appointments.

Case 27. A 53 year old Caucasian female with Type 2 diabetes diagnosed at 45 years of age. She had no known diabetes-related complications. Her diabetes was managed through diet alone. This remained unchanged throughout the study.

Case 28. A 36 year old Caucasian female with Type 2 diabetes diagnosed at 35 years of age. She had no known diabetes-related complications. Her diabetes was managed through diet and medication (Metformin). Her diabetes medication remained unchanged throughout the study.

Case 29. A 43 year old Caucasian male with Type 2 diabetes diagnosed at 35 years of age. He had no known diabetes-related complications. His diabetes was managed through diet alone, which remained unchanged throughout the study.

Appendix 8: Topics covered during MI training (Studies 1-3)

Health belief model

- Perceived probability and seriousness of consequences
- Perceived severity of risk
- Self-efficacy

Dangerous assumptions about behaviour change

- This person ought to change
- This person is ready to change
- This person's health is a prime motivating factor for him/her
- If he/she decides not to change the consultation has failed
- Patients are either motivated to change or not
- Now is the right time to consider change
- A tough approach is always best
- I'm the expert – the patient must follow my advice

Principles of good practice when negotiating behaviour change

- Respect for the autonomy of patients and their choices
- Readiness to change needs to be taken into account
- Ambivalence is common and needs to be understood
- Targets for change should be selected by the patient
- The expert (i.e., health practitioner) is the provider of information and support
- The patient is the active decision-maker

Ingredients for effective brief interventions (FRAMES)

- Feedback - personalised
- Responsibility for change lies with the patient
- Advice – provided in small doses when the patient is ready
- Menu of options provided
- Empathy – conveyed through reflective listening
- Self-efficacy – needed for behaviour change

Principles of MI (REDS)

- Role with resistance
- Express empathy
- Develop discrepancy
- Support self-efficacy

Stages of change

- Pre-contemplation
- Contemplation
- Determination
- Action
- Maintenance

Resistance

- Not an inherent part of pathology
- Observable behaviour
- Fluctuates
- Influenced by practitioner's behaviour

MI skills

- Open-ended questions
- Affirmation
- Reflections
- Summaries

MI strategies

- Importance, confidence and readiness rulers
- Agenda setting
- Typical day
- Personal dissonance
- Good things and the less good things
- Providing information
- Life satisfaction – the present and the future
- Costs and benefits
- Constructing a decision balance
- Helping with decision-making

Appendix 9: Risk Factor Interview Checklist (modified)

At the beginning of the interview, did the practitioner:

	N/A	Not demonstrated	Partially demonstrated	Clearly demonstrated
1 Communicate in a style that facilitated patient understanding and comfort? (eg vocabulary, avoiding highly technical terms)				
2 Explicitly invite the patient to collaborate in assessing their readiness to begin or continue with lifestyle change?				
3 Inquire about the patient's objective for the interview and negotiate focusing on risk factors for diabetes?				

When discussing risk behaviours did the practitioner:

1 Use open-ended questions to explore relevant issues and to facilitate the patient's active involvement?				
2 Allow for occasional silence so that the patient could reflect upon issues related to lifestyle?				
3 Use periodic summary statements to clarify potential barriers or supports for change?				
4 Identify and validate the patient's positive and negative feelings about health risk behaviours?				
5 Help the patient to view prior unsuccessful efforts to change as important learning experiences?				

Before ending the interview, did the practitioner:

1 Invite the patient to note personally relevant issues that may not have been identified in the interview?				
2 Review supports and barriers, and state how change could be achieved in manageable steps?				
3 Express support for the patient's freedom to make an informed choice about whether to proceed with a plan for change at this time?				
4 Negotiate the next step for counselling about change?				
5 Verbally reinforce the patient's effort to discuss, prepare for, or initiate change?				

Appendix 10: MET Audit

RATING SCALE TO AUDIT MET SESSIONS (MODIFIED)

1. How much was this therapy session actively directed by the therapist?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

2. How much was this therapy session focused by the therapist on the patient's diabetes?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

3. How much did the therapist elicit self-motivational statements by the patient?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

4. How much did the therapist use summaries?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

5. How much did the therapist praise or affirm the patient?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

6. How much did the therapist give advice, direction or education to the patient?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

7. How much did the therapist use reflective listening?

<i>not at all</i>	<i>a little</i>	<i>moderately</i>	<i>a lot</i>
	<i>extremely</i>		

8. How much did the therapist use dynamic interpretations?

not at all

*a little
extremely*

moderately

a lot

9. How much did the therapist actively explore non-diabetes issues of the patient in depth?

not at all

*a little
extremely*

moderately

a lot

10. How much was the therapist's style empathic?

not at all

*a little
extremely*

moderately

a lot

Four Categories of Client Resistance Behaviour

1. **ARGUING.** The client contests the accuracy, expertise, or integrity of the therapist.
 - 1a. **Challenging.** The client directly challenges the accuracy of what the therapist has said.
 - 1b. **Discounting.** The client questions the therapist's personal authority and expertise.
 - 1c. **Hostility.** The client expresses direct hostility toward the therapist.
2. **INTERRUPTING.** The client breaks in and interrupts the therapist in a defensive manner.
 - 2a. **Talking over.** The client speaks while the therapist is still talking, without waiting for an appropriate pause or silence.
 - 2b. **Cutting off.** The client breaks in with words obviously intended to cut the therapist off (e.g., "*Now wait a minute. I've heard about enough*").
3. **DENYING.** The client expresses an unwillingness to recognize problems, cooperate, accept responsibility, or take advice.
 - 3a. **Blaming.** The client blames other people for problems.
 - 3b. **Disagreeing.** The client disagrees with a suggestion that the therapist has made, offering no constructive alternative. This includes the familiar "*yes, but...*" which explains what is wrong with suggestions that are made.
 - 3c. **Excusing.** The client makes excuses for his or her own behaviour.
 - 3d. **Claiming impunity.** The client claims that he or she is not in any danger (e.g. from drinking).
 - 3e. **Minimizing.** The client suggests that the therapist is exaggerating risks or dangers, and that it "*really isn't so bad.*"
 - 3f. **Pessimism.** The client makes general statements about self or others that are pessimistic, defeatist, or negativistic in tone.
 - 3g. **Reluctance.** The client expresses reservations and reluctance about information or advice given.
 - 3h. **Unwillingness to change.** The client expresses a lack of desire or an unwillingness to change, or an intention not to change.
4. **IGNORING.** The client shows evidence of not following, or ignoring the therapist.
 - 4a. **Inattention.** The client's response indicates that he or she has not been following or attending to the therapist.
 - 4b. **Nonanswer.** In answering a therapist's query, the client gives a response that is not an answer to the question.
 - 4c. **No response.** The client gives no audible or nonverbal reply to a therapist's query.
 - 4d. **Sidetracking.** The client changes the direction of the conversation that the therapist has been pursuing.

Signs of Readiness for Change

1. **Decreased resistance**
The client stops arguing, interrupting, denying, or objecting.
2. **Decreased questions about the problem**
The client seems to have enough information about his or her problem, and stops asking questions. There is a sense of being finished.
3. **Resolve**
The client appears to have reached a resolution, and may seem more peaceful, relaxed, calm, unburdened, or settled. Sometimes this happens after the client has passed through a period of anguish or tearfulness.
4. **Self-motivational statements**
The client makes direct self-motivational statements (see Chapter 6), reflecting recognition of a problem (*I guess this is serious*), concern (*This worries me*), openness to change (*I need to do something*), or optimism (*I'm going to beat this*).
5. **Increased questions about change**
The client asks what he or she could do about the problem, how people change if they decide to, or the like.
6. **Envisioning**
The client begins to talk about how life might be after a change, to anticipate difficulties if a change were made, or to discuss the advantages of change.
7. **Experimenting**
If the client has had time between sessions, he or she may have begun experimenting with possible change approaches.

Appendix 12: Importance, Confidence and Readiness Rulers

Staff:

Date:.....

Importance

Please indicate (by placing circling the appropriate number) how important you consider Motivational Enhancement Therapy (MET) is to enhancing diabetes self-management, with 1 indicating not important at all and 10 indicating very important:

1 2 3 4 5 6 7 8 9 10

Confidence

Please indicate (by placing an X in the appropriate space) where you consider you are in terms of your confidence to use MET, with 1 indicating not confident and 10 indicating very confident:

1 2 3 4 5 6 7 8 9 10

Readiness Ruler

Please indicate (by placing an X in the appropriate space) where you consider you are in terms of your readiness to use MET, with 1 indicating not ready and 7 indicating ready now.

1 2 3 4 5 6 7

Appendix 13: Motivational Interviewing Knowledge Test

Name:.....

Date:.....

Motivational Interviewing Knowledge Test

1. What is the underlying philosophy of motivational interviewing (MI)?

.....
.....

2. What is the goal of MI?

.....
.....

3. How is empathy expressed in MI?

.....
.....

4. What key client statements should be reflected in MI?

.....
.....

5. List 3 signs of resistance

1.....
2.....
3.....

6. What do you do in MI if you meet resistance?

.....
.....

7. How is ambivalence dealt with in MI?

.....
.....

8. Give 3 examples of change talk

1.....
2.....
3.....

9. List 3 techniques for eliciting change talk

1.....
2.....
3.....

10. List 3 things you should do when giving advice in MI

1.....
2.....
3.....